APHIS Evaluation of the Status of the Republic of Korea Regarding Foot-and-Mouth Disease and Rinderpest

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ABBREVIATIONS

AGRIX	National Animal Identification Database
APHIS	Animal and Plant Health Inspection Service
CFIA	Canadian Food Inspection Agency
CFR	Code of Federal Regulations
CIQ	Customs, Immigration and Quarantine
CPI	Consumer price index
DMZ	Demilitarized zone
ELISA	Enzyme-linked immunosorbent assay
FADD	Foreign Animal Disease Division
FMD	Foot-and-mouth disease
KNC	Korean native cattle
LHCA	Livestock Health Control Association
LPBE	Liquid phase blocking ELISA
MiFAFF	Ministry for Food, Agriculture, Forestry and Fisheries (MIFAFF), formerly the Ministry of Agriculture and Forestry (MAF)
MAF	Ministry of Agriculture and Forestry
NEPA	National Environmental Policy Act
NSP ELISA	Nonstructural protein enzyme-linked immunosorbent assay
NVRQS	National Veterinary Research and Quarantine Service
OIE	Office International des Epizooties (World Organization for Animal Health)
PCR	Polymerase chain reaction
RT-PCR	Reverse transcriptase PCR
Si/Gun/Gu	Si = city; Gun = municipality; Gu = district of a metropolitan city
SOP	Standard operating procedure
USDA	U.S. Department of Agriculture
VN	Virus neutralization

EXECUTIVE SUMMARY

The Republic of Korea submitted a request to the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) seeking recognition for freedom from foot-and-mouth disease (FMD). The last outbreak of FMD in the Republic of Korea occurred in 2002. APHIS conducted a qualitative risk assessment to evaluate the Republic of Korea's disease status regarding FMD and rinderpest.

Korea's Ministry for Food, Agriculture, Forestry and Fisheries (MiFAFF) submitted information to support their request. In addition to evaluating this information, APHIS conducted a joint site visit to Korea with representatives of the Canadian Food Inspection Agency (CFIA) in March 2008 to substantiate Korea's information and obtain additional data. The site visit focused on MiFAFF's veterinary and legal infrastructure, the National Veterinary Research and Quarantine Service (NVRQS), border control procedures, laboratory and diagnostic capabilities, biosecurity procedures on cattle and swine farms and slaughter facilities, movement controls, animal health recordkeeping systems, and disease surveillance systems related to FMD. Supporting documentation for this risk assessment included information submitted by Korea, our observations during the site visit, and technical documents and data from other sources that could inform our evaluation of the likelihood that imports from Korea could introduce FMD into the United States.

APHIS conducted the risk analysis according to World Organization for Animal Health (OIE) guidelines. It includes a hazard identification, release assessment, exposure assessment, consequence assessment, and risk estimate [1]. This document describes the animal health system in Korea, identifies potential areas of risk, and discusses how Korea mitigates this risk.

APHIS considers the legal framework, animal health infrastructure, movement and border controls, diagnostic capabilities, surveillance programs, and emergency response systems to be adequate to detect and control FMD outbreaks within the national boundaries of the region. Extensive surveillance has not detected the presence of the FMD virus. The Republic of Korea does not vaccinate for FMD. If FMD or rinderpest were introduced, it would be detected quickly.

Although consequences of an FMD or rinderpest outbreak in the United States would be severe, the likelihood of an outbreak occurring via exposure of the domestic livestock population to animal or animal products imported from Korea is negligible.

BACKGROUND

The Republic of Korea has officially requested that APHIS recognize the country as free from FMD. The last outbreaks in the country occurred in 2000 and 2002 and were limited in nature and rapidly controlled. No new outbreaks have been reported since then.

MiFAFF's animal health officials submitted documentation to support their request. APHIS conducted a joint site visit with representatives of the CFIA in March 2008 to supplement and substantiate MiFAFF's documentation. This assessment focuses on the legal framework and veterinary infrastructure, border and movement controls, market structure and agricultural practices, laboratory diagnostics and surveillance programs related to Korea's animal health program.

OBJECTIVES

This is an analysis of the risk of introducing FMD or rinderpest into the United States through susceptible species and related unprocessed products imported from the Republic of Korea. The risk analysis is a decision-making tool for APHIS managers that will allow development of appropriate regulatory conditions with mitigations to address potential risks of disease introduction following any initiation of trade. It also constitutes an information source for the public, providing justification for the conditions in the rule. The analysis focuses on the FMD status and control measures applicable to Korea.

HAZARD IDENTIFICATION

APHIS has identified several OIE listed diseases [1] as the primary hazards associated with initiating trade in animals and animal products from foreign regions. APHIS regulations in title 9 of the *Code of Federal Regulations* (9 CFR), part 94, list specific foreign animal diseases of primary concern. Two of these diseases are FMD and rinderpest. APHIS is obligated to conduct an evaluation to support rulemaking (9 CFR 92.2) [9] before initiating trade in FMD- or rinderpest-susceptible species and related products with a region or country that we have not evaluated previously for FMD or rinderpest status.

FMD virus is the identified hazard. In Appendix 1, we describe the epidemiological characteristics relevant to the import risk it may pose.

Regarding rinderpest, the Republic of Korea has not had an outbreak since 1931[13]. Therefore, we propose APHIS recognize Korea as free from rinderpest. In Appendix 2, we describe the epidemiological characteristics relevant to the import risk it may pose.

Figure 1. Map of the Korean Peninsula showing North and South Korea [http://www.lib.utexas.edu/maps/middle_east_and_asia/s_korea_pol_95.pdf]

RISK ANALYSIS

This analysis has four components: the release assessment, the exposure assessment, the consequence assessment, and the risk estimation. OIE guidelines define these components and represent the international recommended components for animal health import risk analysis.

RELEASE ASSESSMENT

For the purpose of this report, release assessment refers to the evaluation of the likelihood that FMD exists in the Republic of Korea and, if so, the likelihood of imports of FMD-susceptible animals or their products from this country introducing the disease into the United States. The report includes an in-depth evaluation of the 11 factors APHIS has identified in 9 CFR 92.2 [9] that must be considered when assessing a region's level of risk.

These factors are:

1. The authority, organization, and infrastructure of the veterinary services organization in the region;
2. Disease status, i.e., whether the restricted disease agent exists in the region;
3. The status of adjacent regions with respect to the agent;
4. The extent of an active disease control program, if any, if the agent is known to exist in the region;
5. The vaccination status of the region;
6. The degree to which the region is separated from adjacent regions of higher risk through physical or other barriers;
7. The extent to which the region controls movement of animals and animal products from regions of higher risk, and the level of biosecurity regarding such movements;
8. Livestock demographics and marketing practices in the region;
9. The type and extent of disease surveillance in the region;
10. Diagnostic laboratory capacity; and
11. Policies and infrastructure for animal disease control in the region.

APHIS identified risk factors from the information we gathered on these topics and discussed applicable mitigations.

MAIN FINDINGS

1. AUTHORITY, ORGANIZATION, AND INFRASTRUCTURE OF THE VETERINARY SERVICES [2-4, 6]

Legal authority

The Act on the Prevention of Contagious Animal Diseases provides the structure of the obligations of State and local Governments to establish a Contagious Animal Disease Control Plan for the prevention and early detection of contagious animal diseases and the development and implementation of emergency programs. The Republic of Korea amended the entire Act on the Prevention of Contagious Animal Diseases with Act No. 6817, December 26, 2002, to reflect the lessons learned in the 2000 and 2002 outbreaks. The Act also provides the authority for the Animal Disease Control Council under the authority of MiFAFF. The Act provides the authority for veterinary officers to carry out animal disease control measures, including the authority to enter livestock holdings for disease control purposes, and obligates the owners of livestock to report suspected disease. The Act also provides for the establishment of the Animal Disease Control Center, which will be responsible for inspection, vaccination, and clinical examination of livestock, the collection of diagnostic or surveillance specimens, premises disinfection, and educational efforts to prevent and control contagious animal diseases.

The Act is further supported by the Enforcement Decree of the Act on the Prevention of Contagious Animal Diseases, as amended by Presidential Decrees No. 18070 (June 29, 2003), No. 18212 (January 9, 2004) and No. 18312 (March 17, 2004). Additional authority is contained in the Enforcement Rule of the Act on the Prevention of Contagious Animal Diseases (Ordinance No. 1448, August 24, 2003), Livestock Sanitation Process Law, Exotic Animal Disease Control Guidelines for FMD and the FMD Control Guidelines.

All regulations related to the control of FMD are based on the Prevention of Contagious Animal Disease and Exotic Animal Disease Control Guidelines. These guidelines describe necessary disease control and preventive measures, including notification of suspicious cases, stamping-out, movement controls, disinfection, vaccination, surveillance, importation quarantine, disposal, compensation, and penal provisions.

The Livestock Sanitation Process Law (Ordinance No.1478, August 4, 2004) provides authority for ante-mortem animal health inspection. The Directive for National Exotic Animal Disease Control Guidelines (Directive No. 1039, last amended August 19, 2000) describes protective measures such as inspection, stamping-out, vaccination, movement controls, and disease management measures that officials should take in the case of an FMD or other exotic animal disease outbreak. This Directive also describes the roles and responsibilities of all parties involved.

Organization and infrastructure of the veterinary services

Major veterinary services responsible for the prevention and control of livestock diseases are the Animal Health Division of MiFAFF, NVRQS, and Provincial Veterinary Services. The Livestock Health Control Association (LHCA), National Agricultural Cooperative Federation, and the Korean Veterinary Medical Association support their activities. On February 29, 2008, the Republic of Korea formed MiFAFF by merging the Ministry of Agriculture and Forestry (MAF) and the Ministry of Maritime Affairs and Fisheries. The previous animal health roles and responsibilities of MiFAFF remained the same as under MAF, and the Director of the Animal Health Team remained as the Chief Veterinary Officer.

The Animal Health Team is a part of the Livestock Policy Bureau under MiFAFF. Its main tasks include the implementation of the Veterinarian Law and Pharmacist Law (for animals), inspection of imported and exported animals or livestock, enforcement of the Domestic Animal Contagious Disease Prevention Law, and the prevention and eradication of domestic animal diseases. The Livestock Products Sanitation Team, also under the Livestock Bureau, is responsible for the application of the Livestock Sanitation Process Law, and the establishment and performance of meat sanitation measures.

NVRQS is an executive agency within MiFAFF tasked with the prevention and control of major animal diseases. NVRQS is headquartered in Anyang (suburban Seoul) and has 5 regional and 15 district offices located across the country. Responsibilities include the quarantine inspection of animals and animal products, livestock product safety, and veterinary research. In December 2001, in response to the 2000 outbreak, NVRQS created the epidemiology division with the primary responsibility of conducting epidemiological investigations and surveillance.

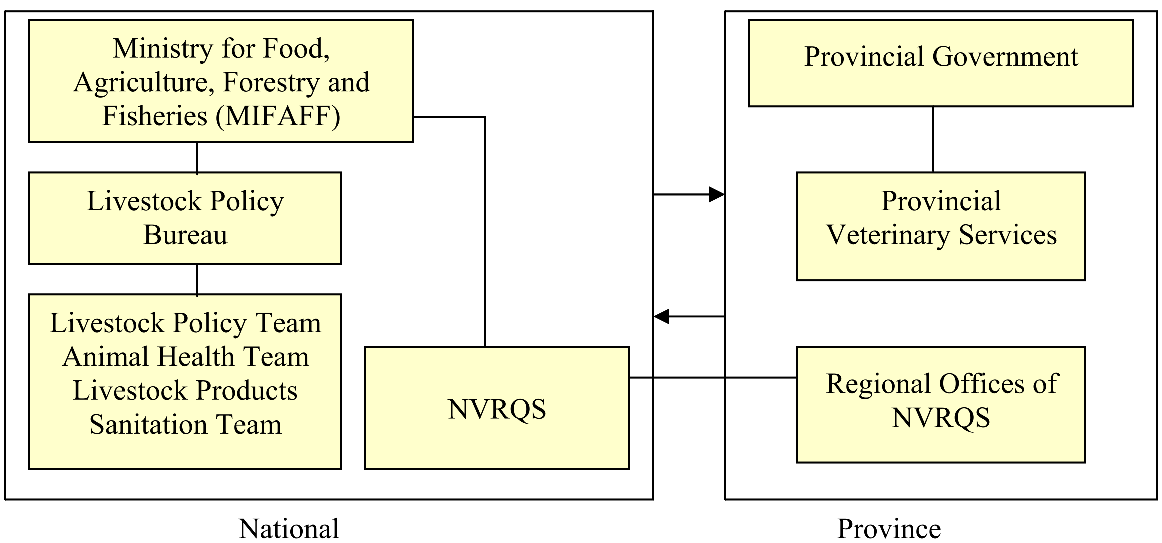

Figure 2. Organization of veterinary services involved in the prevention and control of livestock diseases

Each of Korea's nine provinces and seven metropolitan cities has its own animal health laboratory and veterinary service, which are responsible for the prevention and control of major animal diseases, meat and milk hygiene, and animal welfare within their region. The provincial animal health laboratories are the primary diagnostic laboratory for animal diseases.

The staff of veterinary services consists of veterinarians and other professionals who specialize in livestock management and animal diseases. As of March 2008, there were 548 veterinarians at the central level, including 17 in MiFFAF and 531 in NVRQS, including border veterinarians. At the provincial level, there are 76 veterinarians in the provincial offices and 603 in the animal health laboratories. At the local level (Si/Gun/Gu, or city/municipality/district of a metropolitan city), there are 203 veterinarians. There are 1,500 auxiliary personnel (animal health assistants) in the system. More than 700 veterinarians are employed in food hygiene and meat inspection. There are more than 9,000 licensed (qualified) veterinarians in Korea.

Several nongovernmental veterinary organizations also work in close cooperation with the central and provincial authorities, including the LHCA, the National Agricultural Cooperative Federation, the Korea Veterinary Association, and various trade associations.

The LHCA is a not-for-profit group that works in close coordination with the provincial and the NVRQS regional and central authorities. MiFAFF (60 percent) and the regional government (40 percent) funds the LHCA, which has a central headquarters, 8 provincial branches, 41 local offices, and 392 employees. Over 350 LHCA personnel are located in the local offices including 33 veterinarians, 202 animal health officers, and more than 150 officers involved in livestock product inspections. LHCA also has an additional 350 full time contractors working on several MiFAFF disease programs and performing local surveillance functions.

The Republic of Korea currently has approximately 350,000 farms, most of which are small holdings. The majority of beef cattle holdings (80 percent) are kept on small farms with less than 10 animals, and an additional 17 percent are raised on farms with less than 50 head. Roughly half of all dairy cattle and swine are raised on small- to medium-sized farms. The total sheep population is approximately 1,000 sheep.

Under the June 2000 Act on Livestock Disease Control and Prevention, the government put in place additional new mandatory on-farm hygiene measures. Because MiFAFF considers many of those farms to be too small to have adequate resources to monitor and execute the new mandatory hygiene measures, they designated the LHCA to conduct these functions.

LHCA plays a major role in interacting with the individual farms to support disinfection programs. The LHCA also assists with surveillance and sampling activities for several disease programs (including FMD and high pathogenicity avian influenza), assists with domestic disease control and quarantine, assesses implementation of mandatory biosecurity measures, and provides education and outreach on animal diseases.

The LHCA's role in the FMD program is significant, and includes collecting routine serosurveillance samples; assisting with disease program activities on cattle, goat, and pig farms; and on-farm surveillance for clinical signs and disease during blood sample collection. MiFAFF and NVRQS are responsible for developing the disease surveillance program goals centrally, including FMD serosurveillance, which are then sent to LHCA. LHCA in turn develops the annual sampling plan for each provincial area and implementation plan for monthly collection of program samples. LHCA submits the samples to the local veterinary services laboratory and notifies them of any clinical suspect cases observed during the on-farm visits. LHCA also reports all field observations directly to MiFAFF.

On average, LHCA animal health officers visit farms five times per year. LHCA farm visits also include conducting biosecurity checks, clinical exams, and audits of farm records for disinfection, vaccination, and livestock introductions. LHCA reports results to MiFAFF.

The National Agricultural Cooperative Federation is the largest farmers association in Korea. It supplies animal feed, fertilizers, artificial insemination services, banking services, education and outreach for farmers, and assistance with disinfection for small-scale farms nationwide. The Korea Veterinary Association cooperates with the government in the technical training of veterinarians, advises the veterinary authorities in developing and implementing various animal health policies, and assists with the mobilization of veterinary practitioners in animal health emergencies. Additionally, several related organizations representing various sectors of livestock farming industries are involved in assisting with the government's animal health activities by providing consultations or active participation in animal disease control projects or the promotion of animal health. These groups include the Korea Swine Association, Korea Dairy and Beef Farmers Association, Korea Dairy Industries Association, and the Korea Meat Industries Association.

Conclusions: The Republic of Korea has the veterinary and regulatory infrastructure to detect and control any incursion of FMD into the country. Frequent monitoring of animal premises and movements allows animal health officials to achieve effective surveillance and detection; this would result in the sufficient administration of eradication efforts, if they were needed.

The Republic of Korea realized that there were substantial delays in recognizing and reporting the 2000 FMD outbreak. Since then, animal health officials have made numerous changes to improve recognition, reporting, and diagnosis of suspected outbreaks. They have enacted new regulations to minimize the risk of FMD with increased surveillance and on-farm monitoring. They have also redefined and improved responsibility sharing and coordination between central, regional, provincial, and district offices and laboratories since the FMD outbreaks in 2000 and 2002.

2. DISEASE STATUS IN THE REGION [3, 5, 10]

Korea was free of FMD from 1934 until an outbreak occurred in 2000. The outbreak was first recognized and reported to NVRQS on March 24, 2000, on a small isolated dairy farm (12 milking cows and 3 calves) about 5 kilometers (km) from the demilitarized zone, in Paju city, Kyunggi province. On March 25, NVRQS confirmed the presence of Type O1 Pan-Asia virus and on April 2 isolated the virus. Officials began stamping out on the index farm on March 26. By April 12, officials confirmed FMD on 11 additional farms. Two of the new farms were also in Kyunggi province, eight were in Chungnam province, 150 km south of the first suspected dairy farm, and one was in Chungbuk province, 140 km southwest of the first infected farm. The outbreaks in Chungnam province all occurred within the 10-km-radius protection zone set up around the primary infected farm.

Officials set up protection zones with a radius of 10 km around each infected farm. In the protection zone, officials restricted animal movements, suspended activities such as livestock markets and artificial insemination, and performed emergency vaccination. Officials set up a 20-km surveillance zone around the infected farms with movement restrictions. In both the protection and surveillance zones, officials immediately conducted intensive surveillance with serological testing and extensive clinical and epidemiological investigation. They also investigated and tested all epidemiologically related farms outside the zones.

Extensive serological surveillance in the protection zones found 57 farms to have animals with antibodies against FMD virus. All infected animals were dairy cattle or Korean native cattle (KNC). There was no evidence of infection in pigs. Officials reported the last infected herd on April 15. They continued serological testing through July, testing 5,400 animals on 1,558 farms in the surveillance zone, and 8,863 animals on 2,076 farms in the protection zones. They also performed additional testing in the free areas (3,568 animals on 1,148 farms). In all, officials tested 17,831 animals on 4,782 farms during the outbreak.

Officials administered two rounds of emergency vaccination, vaccinating 860,747 animals in the first round and 640,438 in the second. Officials vaccinated both cattle and swine and permanently marked all vaccinated animals (pigs by ear punch and cattle by branding), and subjected the vaccinated animals to additional serologic testing and clinical examination.

In response to this outbreak, in December 2001, officials created an epidemiology division within NVRQS to conduct ongoing epidemiological investigation and surveillance. They also made changes to animal health regulation in response to the lessons learned during the outbreak.

On May 2, 2002, the Republic of Korea again detected the presence of FMD, based on clinical signs, on a large pig farm in Kyonggi province. The next day, officials detected FMD on a small pig farm in Chungbuk province about 25 km from the first farm. Following the confirmation of FMD, in compliance with the Exotic Animal Disease Control Guidelines and FMD Emergency Standard Operating Procedures (SOP), officials immediately established emergency FMD control centers at MAF and NVRQS to plan and coordinate emergency operations. They also established provincial emergency control centers to implement necessary control measures. Throughout the outbreak, officials held emergency meetings, attended by MAF, NVRQS, veterinary experts, and livestock associations, to manage the implementation of the control strategy.

Officials immediately established control zones around all infected farms, including 3 km around the at-risk zone, 10 km around the protection zone and, a 20-km buffer zone.

Officials implemented an immediate stamping-out policy with movement controls and quarantine. They quickly culled and buried all susceptible animals on infected and neighboring farms within a 500-meter radius. They did not do any emergency vaccinations. Officials found FMD on 16 farms between May 2 and June 23, 2002. They lifted the last control zone on August 7. The affected farms were all pig farms except for two farms with mixed populations:

one with swine and cattle and one with swine and captive deer. However, on those two farms, officials could only determine infection in the swine. All affected farms were located within a 9-km radius of the first two affected farms. Seven of the 16 infected farms were within the 3-km at-risk zone. The greatest distance between the affected farms was less than 30 km.

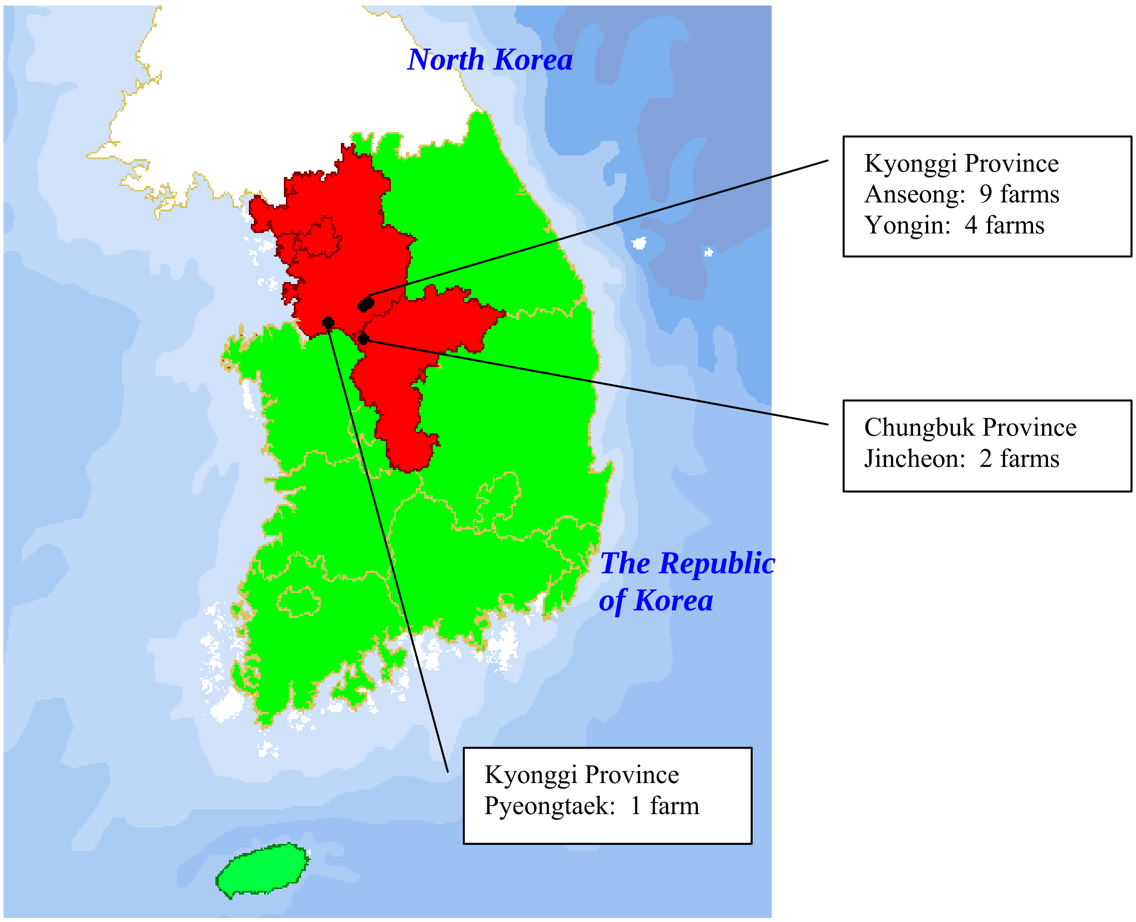

Figure 3. Map showing location of the affected swine farms in the 2002 FMD outbreak.

The epidemiological investigation concluded that the main route of transmission from the index farm to subsequent farms was mechanical transmission by people (pharmaceutical companies, artificial insemination, delivery, participation at slaughter, etc.) and vehicles (feed and sewage trucks, etc.). There was no evidence of direct transmission by movement of pigs. NVRQS epidemiologists diagrammed the potential infectious contacts between infected farms based on their investigations showing the contacts between the index farm and all other affected premises (see figure 4) [10].

In June 2002, the Republic of Korea invited an International Epidemiology Assessment Team from Australia, New Zealand, and the United States to assess the FMD situation and control measures [10]. The International Team found evidence that Korea's stamping out and movement restrictions were effective in containing the spread of disease. Rapid diagnosis using pen-side diagnostic tests enabled rapid detection of infected animals so officials could affect control measures and immediate stamping-out procedures. The International Team concluded that this capability for early diagnosis together with rapid stamping out of infected swine farms has been a key factor in limiting the number of cases in this outbreak.

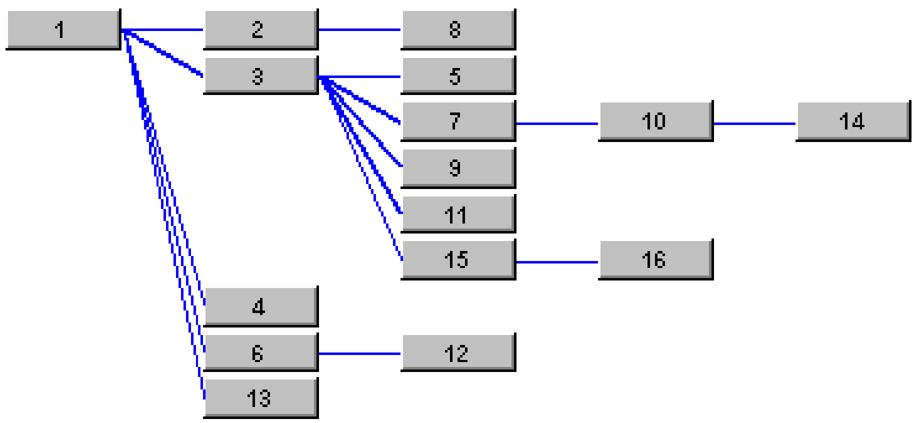

Figure 4. Representative diagram of farm contact in the 2002 outbreak

Officials investigated several possible routes of FMD introduction included foreign workers at index or neighboring farms, direct or indirect contact with overseas travelers, feeding of swill, imported hay or sawdust, and air-borne transmission via "yellow sand." At the time of the FMD outbreak, there were two foreign workers on the index farm. Although there was no direct evidence that the foreign workers had caused the transmission of the disease through hand-carried importation of infective meat or meat products, this was considered to be the most likely source of the infection.

Yellow sand, also known as yellow wind, Korean dust, or China dust storms, is a springtime meteorological phenomenon that affects much of East Asia. The dust originates in the deserts of Mongolia, northern China, and Kazakhstan, and is carried eastward by prevailing winds to South Korea. Officials investigated yellow sand as a possible route of introduction in the 2002 outbreak, collecting 290 yellow sand samples across Korea, and tested them for FMD virus using polymerase chain reaction (PCR). All samples were negative.

FMD has not occurred in Korea since 2002. In addition, vesicular stomatitis, swine vesicular disease, and vesicular exanthema (diseases that must be considered in the differential diagnosis of FMD) have never been reported in the Republic of Korea. Under the Act on the Prevention of Contagious Animal Disease, vesicular stomatitis and swine vesicular disease are notifiable.

Conclusions: The last FMD outbreak in the Republic of Korea occurred in 2002. There is no evidence that there are any species infected with the FMD virus in the Republic of Korea.

3. Disease status of adjacent regions [3, 11]

The Republic of Korea occupies the southern half of the Korean Peninsula. The Republic of Korea and Democratic People's Republic of Korea (North Korea) share the Korean Peninsula, separated by a land/river border referred to as the demilitarized zone (DMZ) that spans the entire 155-mile border between the two countries near the 38^{th} parallel. The DMZ is 2.5 miles wide and serves as an effective buffer zone between the two countries. With the exception of the northern portion of the country, where the Republic of Korea shares a land border with the Democratic People's Republic of Korea, the country is surrounded by water.

FMD must be considered to be endemic in the Democratic People's Republic of Korea, although animal agriculture is limited and that country does not fully participate in international animal organizations. North Korea has sporadically reported outbreaks of FMD to OIE and reported the presence of Asia-1 as recently as 2007, although no reports have yet been made for 2008. During the 2007 outbreak, North Korean officials reported 431 cases in cattle. Information regarding the status of FMD type O was not available. The Republic of Korea provides North Korea with technical assistance and training in an effort to assist with improving North Korea's disease control programs.

The other neighboring countries closest to the Republic of Korea are China to the west and Japan to the east. Korea is separated from these countries by the Yellow Sea and the Sea of Japan. The last reported outbreak of FMD in Japan occurred in March and April 2000 and was limited to three small beef farms.

There are several strains of type O FMD virus circulating in East Asia, including a pig-adapted strain present in the People's Republic of China, including Taipei China and Hong Kong, as well as some other countries in South East Asia. Officials have recovered other strains of type O FMD virus that are not specific to a particular species from sheep, cattle, goats, and pigs; these strains have infected Taiwan yellow and Japanese Holstein cattle without causing clinical signs. This strain was responsible for recent outbreaks in the People's Republic of China, Taipei China, Japan, Russia, and Mongolia [12].

Officials attributed the outbreaks of FMD in Taipei China in 1999 and Mongolia in 2000 to the probable illegal movement of live infected animals from neighboring countries, and the outbreak in eastern Russia to the feeding of pigs with infected products illegally imported from the People's Republic of China or other countries [12]. China, including Hong Kong, has reported cases of FMD (type O and Asia-1) to OIE on a sporadic basis almost yearly and Hong Kong regularly vaccinates for Type O. Officials reported outbreaks of Type O in Mongolia in 2000, 2001, 2002, and 2004, and outbreaks of type A in 2005. The Republic of Korea has been working with Mongolia since 2005 to support their FMD diagnosis and control measures.

Conclusions: At the time of our site visit, FMD had not been diagnosed in the Republic of Korea since 2002. There is no evidence that FMD has been transported from surrounding countries or regions since Korean officials established biosecurity and other disease control measures, described in this document, following the 2000 and 2002 outbreaks.

4. Extent of an active disease control program [3, 5]

Since there is no evidence that FMD is present and no FMD outbreaks have occurred since 2002, there is no active disease control program. However, Korea has a comprehensive surveillance system with active (seroepidemiologic surveillance) and passive (clinical) surveillance components rather than an active disease control program (see section 9 below). In addition to surveillance, there are measures in place, including animal movement controls, border inspection, disinfection, and emergency plans, to prevent the incursion of the disease into the country.

During the 2002 outbreak, farmers did not recognize and report suspect cases immediately. In response to this, and to promote rapid recognition and reporting of possible disease outbreaks, officials wrote indemnification into their animal health law. MiFAFF viewed the legalization and financial support of indemnity as an incentive for farmers to report suspect cases and to deter the movement of sick animals to slaughter or auction. Under the indemnification regulation, MiFAFF sets aside a portion of its budget for compensation for nine program diseases, including FMD. The indemnification covers 100 percent of the market value of animals slaughtered as part of disease control/eradication efforts for these nine diseases. In addition to indemnity, MiFAFF provides farmers with subsistence funding until the farm is functional again. Livestock cooperatives also provide low-interest loans, as well as assistance with feed and management. Support continues for up to 6 months until restocking is complete and the amount provided is proportional to production levels.

Officials provide incentives for reporting suspect cases in the form of a cash reward of 500,000 won (about 400 U.S. dollars (USD)) if the case requires laboratory diagnosis, and one million won (about 800 USD) if FMD is confirmed. An emergency hotline is available to encourage reporting of suspicious cases to the LCHA, and a quarantine hotline receives emergency reports at the border. Officials impose sanctions as a disincentive for the delayed reporting of suspect cases. MiFAFF also provides rewards for third-person reporting of suspect cases as an incentive for early disease identification.

The Act on the Prevention of Contagious Animal Disease includes penal provisions (Articles 56, 57, and 58, and Article 60) and fines that may be levied for negligence. Penalties include imprisonment for not more than 3 years or a fine not exceeding 15 million won (12,000 USD) for veterinarians or farmers failing to report sick or dead animals, importation of prohibited items, or failure to submit goods to quarantine inspection. For livestock owners or transporters who violate articles related to Isolation, Order for Closure of Livestock-Raising Facilities, Suspension of Use of Livestock Collection Facilities, or Restriction on Disposal Carcasses or contaminated goods, penalties consist of imprisonment for not more than 1 year or a fine not exceeding

5 million won (4,000 USD). Fines not exceeding 3 million won (2,400 USD) are levied for any person who refuses, obstructs, or evades an epidemiological investigation; violates provisions of the Prior Notification of Animal Imports requirements; or evades quarantine inspections of goods in the mail.

As part of their FMD disease prevention efforts, the Republic of Korea has also incorporated certain provisions related to garbage control and swill feeding. Article 13 of the Feed Control Act prohibits using swill or garbage for animal feed. Officials monitor the feeding of swill or garbage by periodic sampling and laboratory testing. Use of waste garbage from airplanes and ships is also prohibited.

Because of the predominance of small farms, Korea's training, education, and outreach efforts to increase awareness have targeted small-scale farmers. Informational and disease education programs are organized through the various agricultural cooperatives, which also provide continuous contact and information for farmers, both large scale and small farms. Outreach efforts provide FMD information in six languages so that the material is accessible to foreign agricultural workers. Officials also instituted "National Disinfection Wednesday" with the goal of preventing farmers from becoming complacent about disease control and biosecurity.

Conclusions: The Republic of Korea has a system of notification and involvement of the central authority to investigate any suspect FMD cases with legal provision for indemnity and penalties. Surveillance programs exist to monitor viral activity in various FMD-susceptible species. Disease control programs emphasize surveillance, ongoing awareness campaigns, and routine review of all livestock. These are further described in subsequent sections of this evaluation.

5. VACCINATION STATUS OF THE REGION [3, 5, 10]

The Republic of Korea does not currently practice vaccination. Korea has not vaccinated for FMD since August 2000, when they completed the second round of emergency vaccinations. The country does not produce FMD vaccines, but maintains a vaccine reserve of 300,000 doses of trivalent vaccines containing O1 Manisa, A22 Iraq, and Asia1 Shamir strains. The vaccine is replenished on an annual rotation, and is stored at NVRQS to quickly implement emergency vaccinations, if needed. In addition, NVRQS has a contract to maintain a national FMD antigen bank reserve of 5,000,000 doses at Pirbright (Merial Co.) in the United Kingdom. NVRQS is the only authority permitted to import, maintain, and distribute (in emergency situations) FMD vaccines in Korea [5]. Korea does not permit the administration of serum against FMD.

During the 2002 outbreak, which affected primarily swine, NVRSQ decided not to vaccinate. The International team reviewed this decision and concluded that, under the circumstances of this outbreak, vaccination would not have been advantageous. The time required to achieve immunity with commercial vaccination in pigs takes several weeks and officials determined that many farms would already have been infected when the disease was first recognized. Additionally, a program of emergency vaccination would have masked the presence of the virus and delayed eradication efforts. In fact, at least four farms were incubating disease when officials discovered the first infected farm. Vaccination could have compromised the control of the outbreak. In addition, vaccination teams could have further exacerbated the spread of the virus [10].

Conclusions: The Republic of Korea has not practiced FMD vaccination since the outbreak in 2000. In the absence of vaccination, clinical signs resulting from an incursion of disease should be quickly identified. The country has instituted disincentives for nonreporting of suspect cases, described elsewhere. Korea has a strong system of interaction with the farm community, a generous indemnity program, and supporting animal health regulations; these make it unlikely that clinical signs of FMD would not be reported.

6. SEPARATION FROM ADJACENT REGIONS OF HIGHER RISK [3, 11, 13]

The Republic of Korea is located on the southern Korean peninsula, sharing a land border only with the Democratic People's Republic of Korea. It is surrounded by the Yellow Sea to the west, the East China Sea to the south, and the Sea of Japan (East Sea) to the east. Officials have instituted movement controls and biosecurity measures, described in the next section, to minimize the risk of incursion of the disease through these routes. Officials have reported recent outbreaks of FMD in neighboring countries: China in 2006, Mongolia in 2005, and Russia in 2006 [13]. The most recent outbreak reported in North Korea was in 2006, although the possibility of more recent outbreaks cannot be ruled out.

North and South Korea are separated by a land/river border, referred to as the DMZ, along the entire 155-mile long border between the two countries near the 38th parallel. The DMZ is 2.5 miles wide and serves as an effective buffer zone between the two countries. Although the Democratic People's Republic of Korea is not considered FMD-free, the DMZ provides a geographical as well as military barrier between the two countries. A river also runs along stretches of the DMZ, which is impassable during high tide. The dry sections of the DMZ have been planted with land mines and fencing that serve as a deterrent to human movement and a preventive against animal movement from North Korea into South Korea. The border is also heavily guarded by military on both sides.

No commerce is allowed by land from North Korea. Intentional or inadvertent ingression of animals from this country is prevented by the presence of a river or heavily fenced land-mined dry areas. The South Korean side of the DMZ has double fencing with guard posts at frequent intervals. The site visit team visited the border between the two countries and found the border well defined and heavily patrolled; the team observed many miles of fencing that appeared to be in good repair and of adequate structure to stop the movement of most animals. The part of the Democratic People's Republic of Korea that the team observed across the DMZ consisted of tenement-style buildings fronted by land that appeared to be intended for agriculture. However, at the time of our site visit, the team observed no evidence of agricultural crops or livestock.

NVQRS has also conducted surveillance for FMD in the sparse wild boar population near the DMZ. They encourage hunters to bring wild boar in for sampling and give them a monetary incentive. However, NVRQS indicated that the population numbers of wild boar in the DMZ region appear to be low. To date, all wild boar surveillance test results have been negative.

Conclusions: Water surrounds the Republic of Korea, so access is primarily by air or sea. The border separating the country from the Democratic People's Republic of Korea includes well-maintained double fences, guard outposts at frequent intervals, and a river in sections of the DMZ that serves as a physical barrier.

7. MOVEMENT CONTROL, BIOSECURITY, AND THE EXTENT TO WHICH THE MOVEMENT OF ANIMALS AND ANIMAL PRODUCTS IS CONTROLLED FROM REGIONS OF HIGHER RISK, AND THE LEVEL OF BIOSECURITY REGARDING SUCH MOVEMENTS [2, 3, 5]

The NVRQS and Customs, Immigration and Quarantine administers border controls. Under the Act for Prevention of Livestock Epidemics, livestock and livestock products may enter the country legally by means of 8 designated international airports and 13 maritime ports where animal quarantine officers from the NVRQS inspect them. This Act also prohibits importation of cloven-hoofed live animals, their meat, meat products, or milk from countries or via areas affected with FMD. Therefore, the Republic of Korea prohibits importation of FMD-susceptible live animals and animal products from countries considered at risk for FMD including the Democratic People's Republic of Korea, China, and Vietnam. Additionally, importation of genetic material requires certification from the exporting country that the semen and embryos originated from countries without FMD or rinderpest and that the exporting country has not reported these diseases. Importation of biologics for animal use requires MiFAFF's approval and permission. Other provisions specified in the Act include the treatment of international garbage with sodium carbonate or sodium sulfate prior to incineration by a licensed company, and the treatment of imported hay for feed or bedding.

Commercial imports

The Republic of Korea imports fresh beef and pork, bovine and swine offal, and other livestock products such as skin, hides, and hair from various countries, all of which were considered by OIE to be FMD-free at the time of writing. Table 1 lists the country of origin and volume of import for beef, pork, chicken, and other livestock products from 2005 through 2007.

Importation of live animals requires prior notification and submission of a health certificate, as specified in the Import Health Requirement of the Enforcement Rule of the Act on the Prevention of Contagious Animal Disease. All imported live cloven-hoofed animals are quarantined for a minimum of 15 days. Quarantine inspection is carried out in NVRQS' quarantine facility, which is described later in this section.

Table 1. Country of Origin and Quantities of Imported Livestock Products, 2005-2007

Items	Year	2005		2006		2007	
	Country	Lots	Volume (kg)	Lots	Volume (kg)	Lots	Volume (kg)
Beef	Australia	9,650	-	12,061	12,589	12,589	
	Mexico	375	2,225,468	545	2,829,258	553	2,550,256
	New Zealand	3,853	38,992,908	4,069	39,560,899	4,224	38,369,293
	USA	-	-	-	-	937	14,645,141
	Subtotal		142,600,542		179,405,436		203,195,852
Pork	Austria	438	7,312,022	596	10,970,795	731	14,006,276
	Australia	149	1,179,251	78	691,441	38	320,930
	Belgium	820	16,886,686	909	118,528,733	831	16,852,148
	Canada	982	20,205,959	1,276	22,391,805	1,970	31,919,560
	Chile	1,295	25,357,305	1,276	22,391,805	1,970,	31,919,560
	Denmark	388	8,576,141	465	10,033,823	491	11,100,999
	Spain	333	4,997,713	602	8,261,013	705	11,234,869
	Finland	68	8,997,713	103	1,799,119	117	2,338,051
	France	869	11,291,563	883	18,245,145	1,017	21,562,338
	UK	49	957,841	41	877,174	38	827,497
	Hungary	471	6,866,669	832	9,635,279	749	10,205,797
	Ireland	9	163,411	3	65,272	19	370,807
	Mexico	104	1,823,679	63	893,622	159	1,749,401
	Netherlands	544	9,481,382	510	10,745,878	646	13,502,072
	Poland	402	6,220,704	641	10,152,815	604	11,628,752
	Sweden	59	1,180,518	14	282,457	36	734,742
	Slovakia	-	-	-	-	13	174,537
	USA	2,263	43,129,233	3,366	60,862,029	3,898	70,152,592
	Subtotal	9,270	173,597,821	11,704	210,529,725	13,667	248,186,191
Chicken	Australia	7	2,544	4	1,596	-	-
	Brazil	129	2,358,742	821	18,163,789	837	19,748,322
	Denmark	873	19,633,103	83	1,960,436	64	1,510,290
	France	63	1,637,225	-	-	-	-
	UK	99	2,165,721	-	-	-	-
	US	947	26,968,762	1,244	38,726,081	581	16,670,749
	Subtotal	2,118		2,152		1,482	

Noncommercial traffic

Inspection activities vary among the air and seaports, and depend on the volume of passengers, type of cargo, and country of origin. Increased inspection is directed at passengers and cargo arriving from regions or countries considered to be high-risk. All items confiscated at the air and seaports are bagged in heavy black plastic, doused with disinfectant, sealed, and incinerated. The Incheon, Busan, and Jejoo international ports also use detector dogs to sniff passenger carry-on and checked baggage. The three ports have 42 dogs with 16 handlers among them.

The international airport uses several public notification platforms to inform passengers about agricultural restrictions including electronic message boards, posters, and leaflets pertaining to FMD. At the Incheon International Airport, officials use detector dogs on 31 airlines from 14 countries based on risk. All baggage identified by the detector dogs is tagged with a radio sensor that emits a signal at the pre-exit inspection station. During the site visit, the team observed detector dogs actually identifying passenger luggage. The handler tagged the baggage with an electronic radio sensor that triggered an alarm at the Customs inspection station. The site visit team observed a close working relationship between NVRQS officers and Customs officials.

Passenger and cargo ferry lines provide regular service to and from Japan and China. Seaports that receive passenger ferries from China screen 100 percent of luggage through X-ray machines and officials examine all suspicious items. Passenger traffic between China and the Republic of Korea is heavy. For example, the two terminals at the Incheon Port Passenger Terminal receive an average of 26 weekly arrivals of passenger ferries from China operated by 9 companies. These come from 10 Chinese ports with an average of 7,700 passengers each week.

Under a special agreement recently reached between the Democratic People's Republic of Korea and the Republic of Korea, tour operators with small groups of tourists have been allowed to travel to Northern Korea on cruise ships leaving from the port of Tonghae in Southern Korea, and sailing to the port of Changjon under tightly regulated conditions.

The centralized International Mail Office near the Incheon International Airport processes all international mail. Customs officials offload mail from planes onto conveyers, individually bar code them, and screen packages radiographically. After this, they use detector dogs and tag all suspect packages for agricultural inspection. Sensors divert the tagged packages to a separate line where officials open and inspect them. If they find a suspect article, they subject the package to further inspection to determine if the article is eligible for importation. When officials find ineligible products, such as meat products, they contact the intended receiver to determine if the receiver wants the item returned to the point of origin or incinerated. If there is no response, they incinerate the confiscated items within 15 days. If packages contain both eligible and ineligible items, officials may remove the ineligible items and replace them with a printed warning with educational information before they reseal the package and send it forward.

Foreign workers and overseas travelers

The epidemiological investigation of the 2002 outbreak also considered foreign workers and overseas travelers as a potential source of mechanical transmission of FMD. Subsequently, MiFAFF instituted additional measures at the ports of entry and began outreach programs, available in several languages, targeted toward educating foreign agricultural workers of the risks of FMD. Outreach efforts include the LHCA's distribution of educational material on FMD to farms with foreign workers.

At the ports of entry, a contract company strategically places disinfecting foot mats at passenger disembarkation gates and maintains them. During the site visit, the team observed that most of the disinfecting mats were well saturated with disinfectant, particularly at the Incheon International Airport. In addition, electronic message boards and posters in several languages displayed at passenger disembarkation gates and at customs had information on FMD. At the Incheon International Airport, a public announcement system repeats a recording with information about FMD at regular intervals.

Imported hay and bedding

Korea's agricultural land is limited, requiring them to import some hay and straw from countries known to have endemic FMD, including China and Indonesia (see Table 2). In the 2000 and 2002 outbreaks, officials investigated imported hay and bedding from China as a potential source of FMD. After testing many samples, they found no evidence of FMD virus in any imported forages.

Based on concerns raised during the outbreaks, officials changed the Animal Health Requirements for Straw and Forage and incorporated those changes into the Act for Prevention of Livestock Epidemics. This Act requires the exporting region be free from FMD for at least 2 years and from rinderpest and African swine fever for at least 3 years. Straw and forage must be properly stored and unexposed to cloven-hoofed animals and their excretions during the process of production, packing, and storage. Before farms can import hay from countries where FMD occurs, the exporters must either steam-treat the forages in an airtight chamber at a minimum temperature of 80˚C for at least 10 minutes, or fumigate it with 35-40 percent formalin solution in a chamber closed for at least 8 hours at a minimum temperature of 19˚C in a Republic of Korea-approved facility. Imported hay undergoes a second disinfection upon entry into the country.

Table 2. Country of Origin and Quantities of Imported Hay for Feed, 2005-2007

Country	2005		2006		2007	
	case	quantity (tons)	case	quantity (tons)	case	quantity (tons)
Australia	402	50,253	597	74,073	463	59,070
Canada	461	47,993	414	42,131	358	34,826
Chile	-	-	-	-	1	91
China	150	18,524	131	16,805	174	29,570
Germany	5	591	1	120	-	-
Spain	-	-	-	-	12	3,859
Indonesia	1	47	5	398	5	220
Japan	-	-	2	0.4	4	0.5
New Zealand	-	-	1	42	-	-
U.S.A	5,277	557,907	5,626	606,198	6,849	727,771
Total	**6,296**	**675,316**	**6,777**	**739,767**	**7,866**	**855,408**

Movement controls within the Republic of Korea

Local livestock cooperatives established under the Agricultural Cooperatives Act are primarily responsible for moving animals from farm to slaughter. These cooperatives establish markets and own the slaughter channel, feed mills, and support services that provide an integrated marketing system even for small farms. The Agricultural Cooperatives Act requires these cooperatives work closely with local veterinary authorities to monitor movements of animals and products.

MiFAFF is piloting a broad-based national animal identification database (AGRIX) based on a database originally developed for the brucellosis program. The AGRIX system focuses on improved recordkeeping for small farms and will address animal movement control. This traceability system uses a unique farm number, a 15-digit animal identification number, and a bar-code system to allow farm-to-table tracking of meat cuts. This traceability system also incorporates ear-tagging and livestock farm registration. The AGRIX database is currently functioning at the Si/Gun level to record animal movement information.

The Livestock Epidemic Prevention Act requires farmers to keep track of all sales transactions and purchases, including seller and buyer data, certificates of testing, and history of vaccinations for program diseases prior to movement. Movement certificates issued by the provincial veterinary services are required for all trade. MiFAFF's national animal tracing system will also include this information.

The beef traceability database is designed to incorporate farm location and inventory with associated unique eartag numbers. When an animal is born on that farm, the farmer adds the farm's address, its unique premises number, and a description of the animal's characteristics and date of birth to the database. When the animal moves to another farm, the farm-related information and premises number is updated. When that animal is slaughtered, it is assigned a unique 15-digit number. Processors have the ability to barcode various cuts with that number, which accompanies the products to the point of sale. Using the barcode information, a consumer can go to the internet and pull up the history of the animal.

MiFAFF intends to link the AGRIX database to the current slaughter and processing database. Other available databases may eventually be integrated into the AGRIX system. At the time of our site visit, some cooperatives and packing plants, representing around 30 percent of cattle production, had implemented the traceability system that was launched in 2007. MiFAFF is targeting full nationwide implementation in 2009 when a law requiring traceability will come into effect.

Quarantine Facilities

NVRQS Quarantine and Inspection Division maintains a quarantine station on Youngjong Island, an isolated peninsula near the Incheon airport (see Appendix 3). There are a total of 11 personnel working on site: 4 quarantine officers, 4 technical officers, and 3 security officers. The quarantine station, which opened in 2001 at the same time as the Incheon International airport, has a total area of 178,646 square miles with 10 cattle barns (with less than 850-head capacity), 6 swine barns (300-head capacity), 3 barns for horses, 1 for deer, and 2 for honeybees. For biosecurity purposes, a dedicated caretaker is assigned to a single building when animals are housed there. Vehicles go through an automatic disinfectant spray before entering areas with quarantine houses. The facility also has administration and other buildings, including a small freezer facility for products flown into Incheon airport, and a large incinerator with a 600-kg/hr capacity to handle all confiscated products seized at the ports.

Swine and cattle are quarantined for 15 days and inspected daily. In 2007, the facility received 307 live animal shipments totaling 7,524 animals of various species, including 29 shipments of breeding swine totaling 182 pigs. Bovine spongiform encephalopathy controls limit cattle imports to breeding cattle. In 2007, the country imported 6 head of cattle from the United States, and in 2006, 2,252 Australian cattle came through the facility.

Most beef and pork products enter through the Busan seaport; only small amounts come in through the Incheon airport. There is a larger freezer facility near the Busan seaport for meat (beef/pork) products awaiting inspection.

Conclusions: APHIS considers the Republic of Korea to have adequate controls at ports of entry for legal commercial importation of FMD-susceptible species and livestock products. The country has instituted additional measures for imports from high-risk countries and products. In response to outcomes of the epidemiological investigations from the 2000 and 2002 outbreaks, Korea has written into regulation and implemented specific measures to address the implicated sources of FMD.

8. LIVESTOCK DEMOGRAPHICS AND MARKETING [2, 3, 14, 15, 16]

The terrain in the Republic of Korea is mountainous and not conducive to extensive agricultural production and crop farming. The lowlands, located to the west and southeast of the peninsula, are an exception, but comprise only 30 percent of the total land area. Most of the country's livestock production and marketing is located in these regions.

The Republic of Korea produces less than 50 percent of its total beef consumption, which, in 2006, was 331,000 tons with 179,000 tons imported. In that same year, the country also produced 71 percent of its milk consumption domestically, which was 2.2 million tons, importing 882,000 tons.

Pig farms also tend to be small, although the current trend is toward larger and more modern farms. Pork production has increased over the last 10 years. The Republic of Korea now produces 76 percent of its total pork consumption, which, in 2006, was 670,000 tons, with 211,000 tons imported.

The nation's cattle population is approximately 2.6 million; the swine population has increased to approximately 10 million (Table 3). Low-density cattle production is predominant, with more than 80 percent of farmers owning fewer than 100 animals. Other farmed FMD-susceptible species are in small numbers; there is a population of 2 million farmed deer on 175,384 premises and less than 2,000 goats.

Beef cattle are primarily traditional KNC, called Hanwoo; the current national herd is around 2.5 million head. Consumer preferences lean strongly toward beef produced from KNC (Table 4). Over the past decade, the government, beef producers, and cooperatives have made efforts to improve the quality and marketability of Hanwoo beef. Recent changes have included limiting the number of cooperatives and brand names marketing Hanwoo as a high quality beef product, revising the Hanwoo beef grading system, differential labeling of domestic versus imported beef products, and implementing a traceability system for KNC cattle.

Livestock cooperatives, established under the Agricultural Cooperatives Act, are an important component of the livestock marketing system. To maintain membership in a cooperative and market beef under its brand name, farmers must adhere to certain quality standards established by the cooperative. At the time of our site visit, the Korean government had limited the current number of Hanwoo brands to 37 to minimize variation across brands.

Table 3. Cattle and swine population by year

Year	Cattle	Swine
1980	1,541,000	1,784,000
1990	2,126,000	4,528,000
1995	3,147,000	6,461,000
2000	2,343,000	8,126,000
2001	1,954,000	8,720,000
2002	1,944,000	8,974,000
2003	1,999,000	9,230,000
2004	2,163,000	8,908,000
2005	2,298,000	8,962,000
2006	2,484,000	9,382,000
2007	2,504,000	9,345,000

Table 4. MAF Livestock statistics, 2000, by province

Province	Korean Native Cattle		Dairy		Swine	
	Farms	Animals	Farms	Animals	Farms	Animals
Kyonggi	19,763	179,000	5,560	212,000	3,644	2,071,000
Kangwon	23,908	122,000	652	24,000	931	356,000
Chungbuk	20,968	127,000	813	31,000	710	389,000
Chungnam	42,825	265,000	2,303	87,000	4,419	1.312,000
Chonbuk	29,491	170,000	983	43,000	2,994	913,000
Chonnnam	65,853	267,000	896	40,000	5,564	785,000
Kyongbuk	63,522	364,000	1,345	57,000	2,156	995,000
Kongnam	64,760	280,000	1,043	43,000	3,908	987,000
Cheju	1,166	27,000	90	5,000	313	317,000
Total	326,256	1,801,000	13,775	543,000	24,639	8,126,000

Conclusions: The Republic of Korea is not a self-sufficient producer of meat and meat products, importing a large portion of meat. The most likely product Korea would export to the United States would be specialized products, specifically Hanwoo beef produced from KNC. APHIS concludes that the biosecurity measures and controls at major production facilities are effective in the prevention of FMD outbreaks. There appears to be high awareness and compliance with these measures. APHIS did not identify significant risk pathways to consider commercial cattle operations as a likely source for introducing FMD into the United States.

9. DISEASE SURVEILLANCE IN THE REGION [2, 3, 18]

The Republic of Korea has an extensive multifaceted surveillance system with both active and passive surveillance components (see Figure 5). The active surveillance component incorporates statistical and purposive sampling, while the passive surveillance includes reporting and followup of suspect cases. The central NVRQS laboratory in Anyang conducts all confirmatory testing. Officials conduct intensive followup of suspicious samples in conjunction with confirmatory testing, quarantine, and other necessary controls.

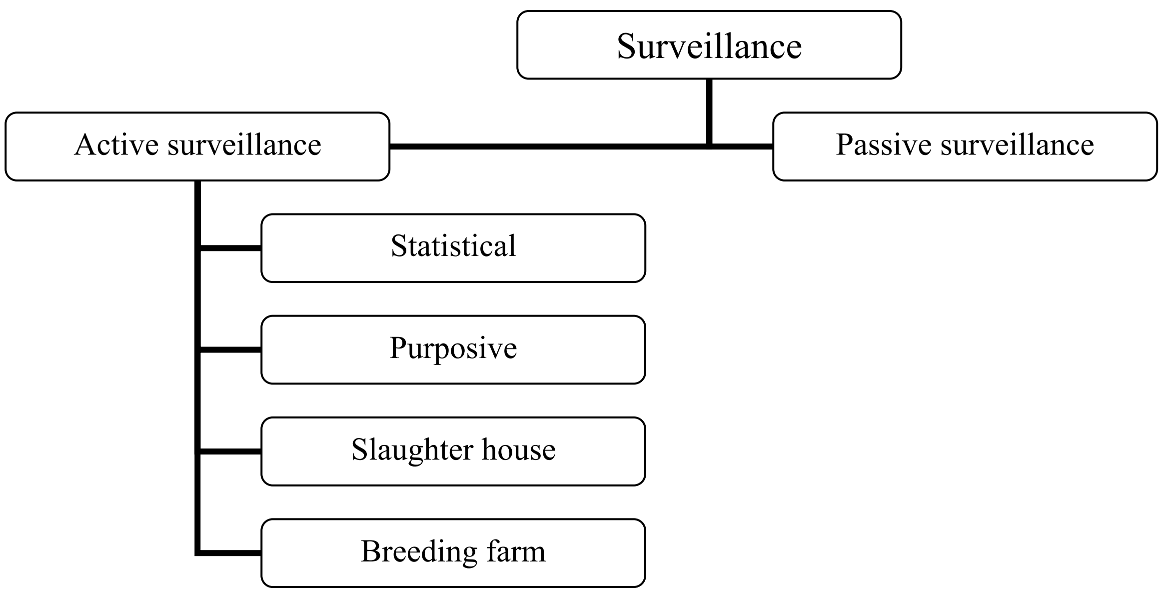

Figure 5. Components of the surveillance system

Active surveillance

Following the 2000 outbreak, the Republic of Korea expanded its active surveillance system. The country organized clinical surveillance teams to make periodic farm visits and clinically examine all livestock. Teams composed of government officers, practicing veterinarians, the National Agricultural Cooperative Federation, and the LHCA are responsible for the surveillance. Each team visits at least five farms a week, checking for clinical signs of FMD.

The teams visit each farm an average of five times each year. The teams report any suspected case immediately to the Si/Gun/Gu Mayor and the regional Animal Health Laboratory.

In March 2002, the government implemented intensified serological surveillance as part of the National FMD Surveillance Program. The serological components of the active surveillance program consist of collecting statistically selected samples ("statistical surveillance") as well as samples from targeted populations ("purposive surveillance").

The statistical surveillance component uses a stratified two-stage sampling strategy to select samples from susceptible populations; the first stage involves selection of farms (herds) from which to collect samples and the second stage is selection of animals within the herd to test. The teams calculate annual sample sizes to provide 99 percent probability of detecting FMD if it is present in the host population at a prevalence of 1 percent (among-herd prevalence). Within-herd sampling is aimed at detecting FMD at a prevalence level of 20 percent for cattle, 29 percent for goats, and 50 percent for pigs. Sample size calculations apply the methodology of M.G. Garner et al., 1997 [17]. To provide a practical minimum farm size but still represent the whole population, all holdings with at least five head of cattle, goats, or pigs are included in the eligible population for surveillance. Farms are randomly selected based on the data provided by regional governments and proportional to the total number of farms in each province. Taking into account that the livestock industry in this country predominantly consists of small farms, the number of samples collected for each farm sampled is four per farm for cattle and goats and eight per farm for pigs.

The objective of the purposive surveillance component is to look for the presence of disease in high-risk areas, situations, or animals (including wildlife) not covered by the statistical surveillance sampling. Purposive surveillance targets high-consequence farms, which include those farms considered to be at higher risk for disease based on animal movement patterns or high-value enterprises such as those raising breeding stock. Samples are collected from high-risk farms during animal movements, from farms raising primarily breeding animals, or at the request of the farm owner.

Samples collected under the statistical and purposive surveillance components are tested using the nonstructural protein enzyme-linked immunosorbent assay (NSP ELISA) test, an OIE-prescribed test for international trade and the OIE-preferred procedure for the detection of FMD viral antigen and identification of viral serotype. Statistical and purposive surveillance data for 2003 through 2007 are shown in Table 5.

Table 5. FMD surveillance samples, 2003- 2007

ELISA	2003		2004		2005		2006		2007	
	Farms	Animals	Farms	Animals	Farms	Animals	Farms	Animals	Farms	Animals
Statistical	2,200	11,700	2,261	12,180	2,287	11,647	1,951	9,655	2,089	10,504
Purposive	1,299	7,889	1,152	6,598	1,437	7,101	1,603	9,903	2,464	15,761
Total	**3,499**	**19, 589**	**3,413**	**18,778**	**3,724**	**18,748**	**3,554**	**19,558**	**10,594**	**61,728**

In addition to the statistical and purposive surveillance components, the Republic of Korea's active surveillance system also incorporates a slaughterhouse and breeding farm surveillance component that uses a rapid "penside" test. Korea developed the penside test to enhance early detection of FMD-infected animals during an outbreak situation. This test is a solid-phase immunochromatographic assay for detection of antibodies to nonstructural proteins, in particular the 2C and 3ABC protein [18], and is currently widely used at slaughter and on breeding farms to augment other active surveillance efforts. Table 6 shows breeding farm and slaughterhouse surveillance results using this test for 2004 through 2007. Table 7 shows the numbers of "false" positive or inconclusive penside tests that officials followed up with the NSP ELISA. All these samples have tested negative for FMD [2].

Table 6. Penside samples performed for FMD surveillance, 2004 -2007

Penside test	2004		2005		2006		2007	
	Farms	Animals	Farms	Animals	Farms	Animals	Farms	Animals
Slaughterhouse	9,826	61,136	11,543	65,848	9,109	55,754	10,594	61,728
Breeding farm	560	20,791	663	25,432	665	23,516	652	22,218
Total	**10,386**	**81,927**	**12,206**	**91,280**	**9,774**	**79,270**	**15,799**	**110,211**

Table 7. Penside test "false" positive or inconclusive results requiring confirmatory followup

Penside test	2004		2005		2006	
	Samples	False positive	Samples	False positive	Samples	False positive
Slaughterhouse	61,136	119	65,848	187	55,754	290
Breeding farm	20,791	47	25,432	47	23,516	85
Total	81,927	166	91,280	234	79,270	375

Sampling strategies and goals are developed at the national level and implemented at the provincial level. Each provincial authority has its own veterinary service responsible for collecting samples from farms and slaughterhouses in their respective province, and animal health laboratory that performs routine serological tests for the FMD surveillance program. Officials report results monthly to the NVRQS. The provincial veterinary officer carries out all initial on-farm investigations and clinical examinations for all suspect cases and reports serological test results. If followup is warranted, the provincial veterinary service notifies the regional government and NVRQS who, in turn, conduct appropriate followup measures according to the FMD emergency SOP.

In compliance with the Act on the Prevention of Contagious Animal Disease, NVRQS performs all confirmatory testing on samples that test positive during any serosurveillance activity and conducts followup, further sampling, and diagnosis of all officially notified suspect cases showing clinical signs.

The local authority will restrict any farm with animals showing positive or inconclusive test results from moving animals until confirmatory testing at the NVRQS central diagnostic laboratory shows that the animals are negative for FMD. If necessary, officials will collect additional samples at the farm, including Probang test samples.

Passive surveillance
In addition to the national active surveillance program, there is passive surveillance for all clinical suspects reported by farmers, veterinarians, or other animal health officials. Under the Act for the Prevention of Livestock Epidemics, it is mandatory to report any FMD-suspicious cases to the local veterinary services. NVRSQ has a well-established course of action for handling all reported suspect cases of FMD.

Officials handle investigations of suspected cases according to the schematic in Figure 6. The provincial veterinary services initially investigate all reports and collect samples for any suspicious cases. Epidemiological teams from NVRQS further investigates all suspicious clinical investigations or suspect test results. The national laboratory evaluates additional diagnostic samples. The provincial laboratories are able to handle basic FMD diagnostics so NVRQS only investigates instances that are highly suspicious (see Table 8).

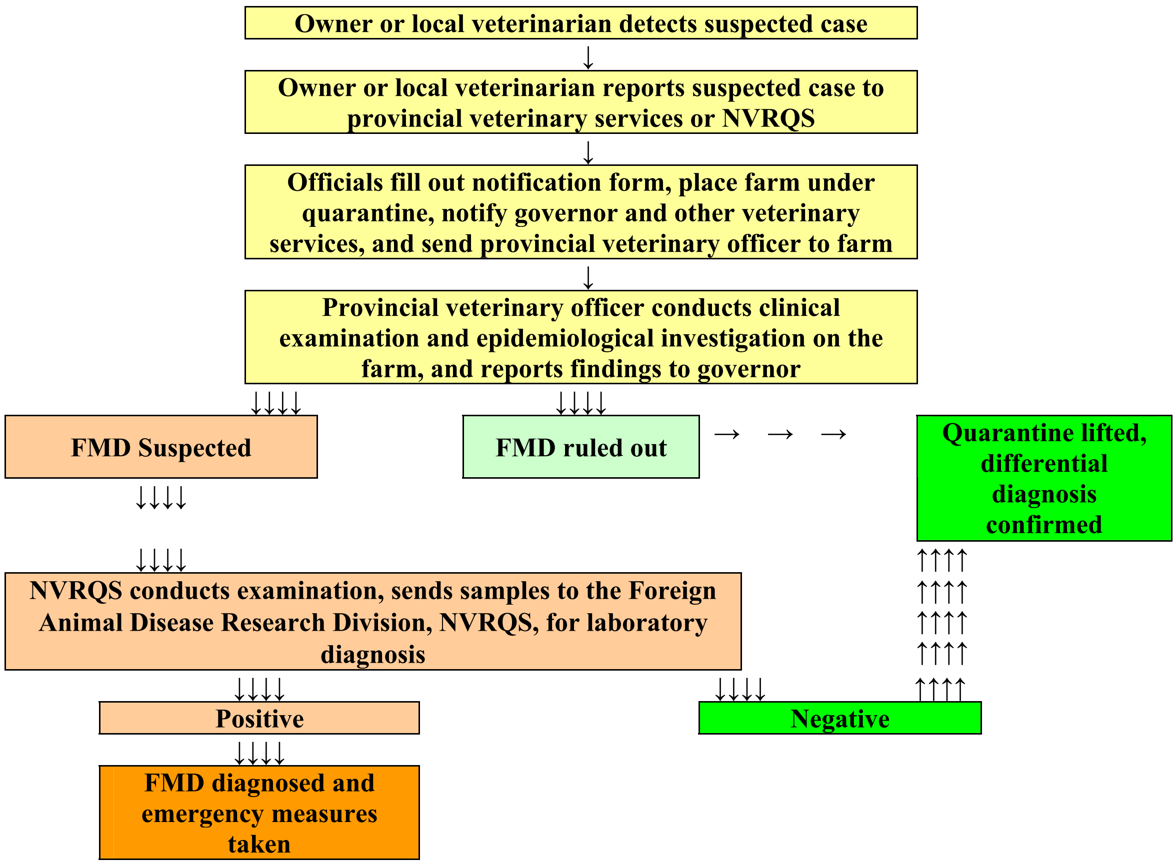

Figure 6. Schematic for handling suspected FMD cases [3]

Table 8. Clinical investigations done by NVRQS by year, 2005-2007

	Total		Cattle		Pigs		Goats	
	Farms	Animals	Farms	Animals	Farms	Animals	Farms	Animals
2005	2	5	2	5	-	-	-	-
2006	7	32	5	17	1	11	1	4
2007	8	51	6	8	1	3	1	40
Total	17	88	13	30	2	14	2	44

By way of example, in Kyonggido province, a summary of the cases investigated indicated that the investigations were primarily on smaller farms with very few clinically affected animals (see Table 9).

Table 9. Reported suspect cases in Kyonggido province, 2003- 2007

Date	Species	Farm size	No. cases	No. deaths	Clinical signs	Final Diagnosis
3/12/2003	Bovine-KNC	9	1	0	Fever, erosions	BVD
3/19/2003	Bovine-KNC	20	2	0	Diarrhea, oral ulcer	BVD
5/29/2003	Bovine-Holstein	50	9	0	Teat blister	Milking equipment problem
11/19/2003	Bovine-KNC	29	1	0	Fever, anorexia	wound
4/1/2004	Bovine-Holstein	62	1	0	Teat blister	Milking equipment problem
5/12/2006	Pigs	2,000	11	0	Hoof edema	Dermatitis
5/25/2007	Bovine-KNC	80	1	0	Wart in nose	Wart
10/2/2007	Pigs	3,7000	3	0	Ataxia	arthritis

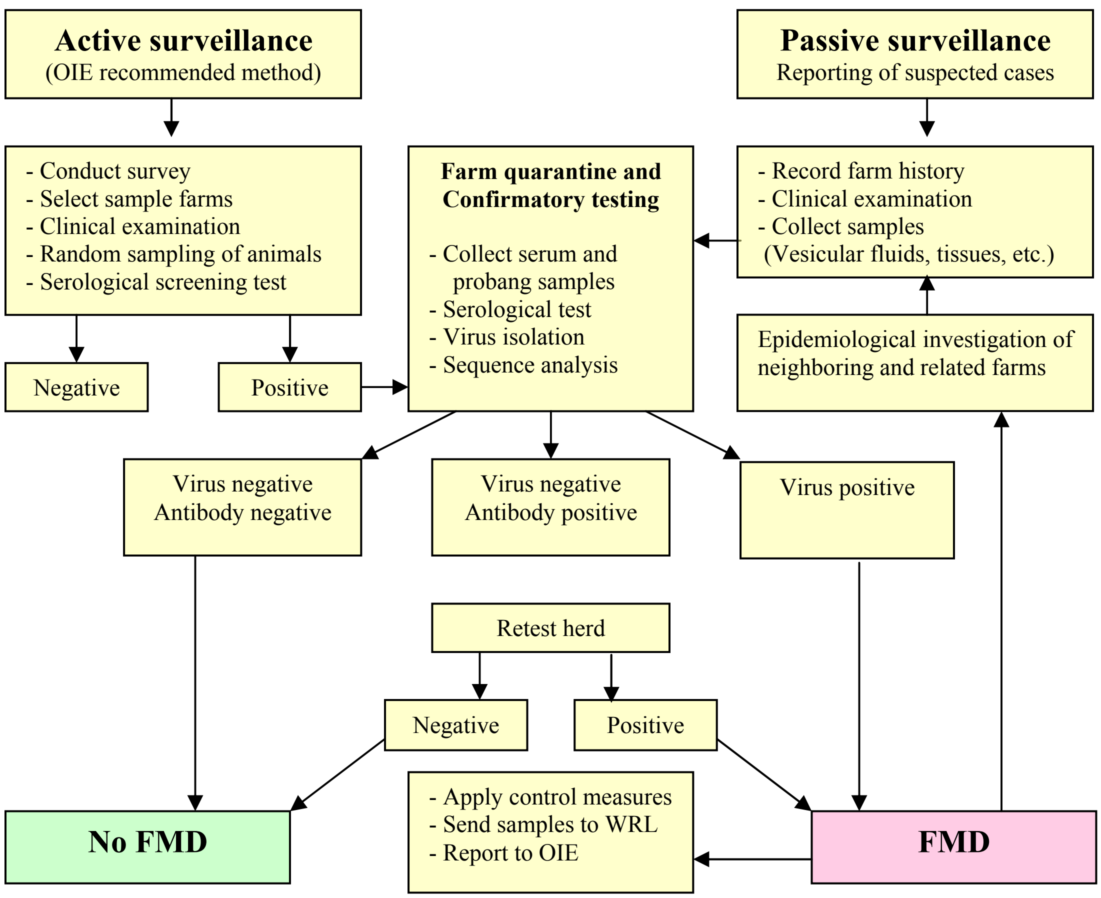

Figure 7. Schematic relationship of active and passive surveillance pathways

Conclusions: APHIS believes that the sampling design that the Republic of Korea uses to conduct serological sampling is both valid and efficient and that the sampling coverage is adequate. APHIS also believes that the serological sampling under the national serological surveillance plan, and the additional sampling using the penside test since the 2002 outbreak, are adequate to detect disease and identify and measure viral activity in the area. Furthermore, the historical absence of disease in the region and the ability to quickly detect the disease if it is introduced in the absence of vaccination further support evidence of the absence of disease in the Republic of Korea.

10. DIAGNOSTIC LABORATORY CAPABILITY [2, 3]

During the 2000 and 2002 outbreaks, NVRQS rapidly confirmed the diagnosis of FMD. Clinically, officials suspected the presence of FMD on March 24, 2000, and NVRQS confirmed it the next day. The diagnostic laboratory used several methods to identify Type O1 Pan-Asia virus: reverse transcriptase (RT) PCR, using 3D PCR of the internal ribosome entry site (IRES)(2) and 1D common regions; ELISA for viral antigen typing; antibody detection, using liquid-phase blocking ELISA; positive indirect ELISA, using recombinant 3D PCR; and transmission electron microscopy to detect virus particles in vesicular fluid.

On April 2, 2000, NVRSQ isolated the virus. NVRQS conducted the sequence analysis of the VP1 gene, and the OIE reference laboratory (Pirbright) showed a close similarity to the FMD virus serotype O/TAW/1/99 and O/Kinmen/TAW/99).

In 2002, NRVQS was again able to rapidly diagnose the presence of FMD using viral antigen typing by antigen ELISA, RT-PCR, and DNA sequencing (partial VP1 region). Although the virus isolated was also type O, officials considered it different from the 2000 virus; instead, they determined it was related to the strains responsible for the 2001 outbreaks in countries such as Mongolia, Russia, China, and Tibet.

Laboratory structure and organization

At present, nine provincial veterinary laboratories, one for each province, perform serological screening as part of the national FMD surveillance program. Investigations and subsequent testing of suspect cases are mainly conducted at the regional laboratories, but all nonspecific or suspect serologic samples are sent to NVRQS for confirmation. The Foreign Animal Disease Research Division of the Foreign Animal Disease Division (FADD) within NVRQS makes the final diagnosis for FMD. FADD, with a staff of 38, has primary responsibility for the diagnosis of infectious foreign animal diseases and for the research. NVRQS received 21 samples from 7 farms in 2006; they received 3 samples in 2007. Testing with liquid phase blocking ELISA (LPBE) determined all samples were negative.

Table 10. Tests employed to diagnose FMD in Korea during the 2002 outbreak

	Test	Method
Antibody test	LPBE 3ABC ELISA Virus Neutralization	International Reference Laboratory, Pirbright UK Foreign Animal Disease Diagnostic Laboratory, USA, Brecia Italy (Using IBRS-2 cells)
Antigen test	Virus Isolation test RT-PCR Antigen ELISA	Using black goat fetal lung (BGFL) Primary cell culture, IBRS-2, BHK/20 Using primers for 3ABC and VPI region WRL Pirbright UK

Required procedures for sample collection and testing

The FMD Control Guidelines outline sample collection procedures. Samples collected for suspect cases include whole blood and serum, and vesicular fluid or epithelial tissues from a lesion. Several laboratory tests available for FMD viral antigen detection include Antigen ELISA, RT-PCR, DNA sequencing and virus isolation, while laboratory tests for FMD antibody detection include liquid phase blocking ELISA (LPBE), 3ABC ELISA, and virus neutralization (VN) test (see Table 10). Officials base procedures for sample handling and testing on OIE specifications.

During a suspected outbreak, tests simultaneously screen samples for the presence of both antigen and antibodies. The laboratory screens serologic samples, and then titrate positive samples by VN. If the laboratory finds any individual positive samples, officials institute movement restrictions and re-sample the entire herd with LPBE, VN, Probang, PCR, and virus isolation. The laboratory processes samples from clinical suspects to get a fully characterized diagnosis in a short time period. The schematic below shows the sample flow chart (see Figure 8).

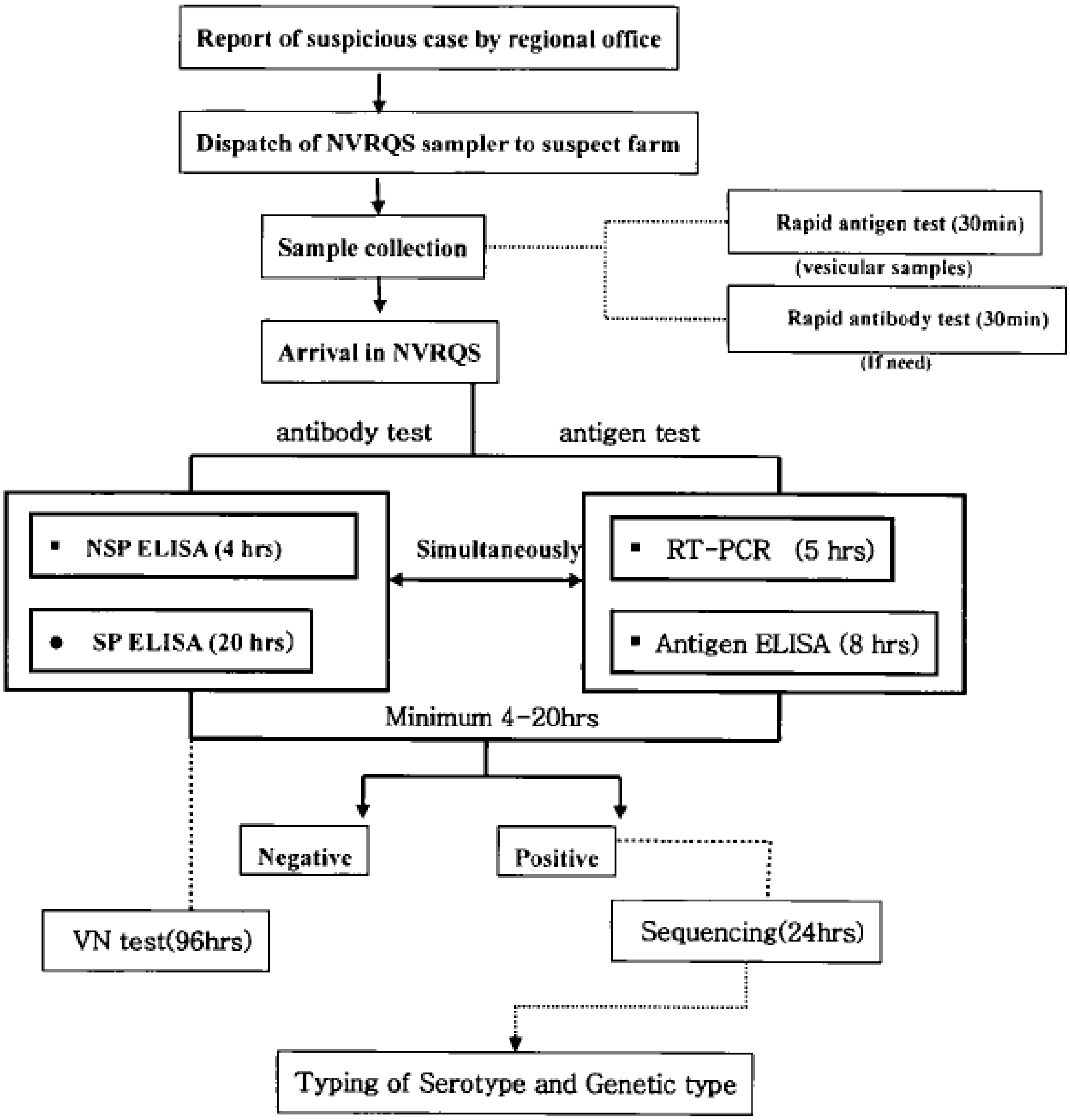

Figure 8. Flow chart for clinical FMD suspect samples with time estimates

Education and training of laboratory personnel

Although the OIE/United Nations Food and Agriculture Organization's FMD proficiency test is not compulsory, the Republic of Korea participated in the test in 2006 as a training opportunity for their laboratory personnel. NVRQS has tentative plans to participate in the FMD proficiency test again in 2009.

All staff performing FMD diagnostics in the provincial laboratories receives annual training for FMD serological tests. In addition, NVRQS provides annual training for all diagnostic laboratory staff in diagnosing FMD, providing training in antibody or antigen ELISA, RT-PCR, sequencing, VN, and the penside test. The laboratory staff has also had training workshops for FMD diagnostics using PCR in Mongolia in 2007 and 2008, and in the Democratic People's Republic of Korea in 2007.

Laboratory personnel must sign a form prohibiting them from having contact with farms and animals for 1 week after handling "foreign infectious animal disease virus" in the biosafety level 3 facility.

Conclusions: The Republic of Korea has adequate diagnostic capabilities to test samples for the FMD virus, including adequate quality control activities, laboratory equipment, and sufficient staff.

11. EMERGENCY RESPONSE CAPABILITY [3, 5]

The Act for the Prevention of Domestic Animal Diseases gives MiFAFF the authority to take immediate control measures in an animal health emergency. The Directive for FMD control in the Manual of Animal Disease Control and the FMD Emergency Control Guidelines describes the contingency plan and specific response. The FMD Emergency Control Guidelines document is a detailed SOP describing the appropriate procedures for officials during an FMD emergency. It was used extensively during the 2002 FMD outbreak. Officials have updated the Guidelines since then to incorporate updates and improvements based on the review of the response to the outbreak.

MiFAFF holds annual contingency exercises every year to test emergency operating procedures and the readiness of the veterinary services in a simulated outbreak. The central and provincial governments hold annual command post exercises that also involve the animal health laboratories and the Si/Gun/Gu. During the exercises, participants practice a range of control measures, including notification of a suspicious case, epidemiological investigation, stamping-out of animals in infected and neighboring farms, movement controls, disinfection activities, surveillance, and compensation. After they complete the program, officials evaluate the participants' performance and make changes, as necessary.

Officials use the livestock industry development fund in the event of major livestock disease outbreaks such as FMD. The fund is for enforcement of preventive measures, and government indemnity and compensation ("buy-out program") for slaughtering infected and exposed animals.

MiFFAF maintains an emergency action plan detailing the roles and responsibilities of MiFAFF, NVRQS, municipalities, veterinary services in cities and provinces, livestock associations, and individual farmers. MiFFAF takes the lead in monitoring potentially higher risk by regularly checking on FMD outbreaks in neighboring countries such as China, Russia, and North Korea.

The emergency plan describes the role of each sector following the discovery of suspect animals from outbreak confirmation, through eradication and follow up, to closing out the outbreak. The plan requires officials to notify OIE within 24 hours of discovery of the disease with followup notification of the final diagnosis, and a report of subsequent control measures.

In the event of an FMD outbreak, MiFAFF establishes emergency headquarters, and then organizes and implements emergency control measures, budgetary allocations, and press reports. However, additional government agencies assist them.

The FMD Emergency SOP and related guidelines specify these agencies' roles and responsibilities:

1. NVRQS supports diagnosis; epidemiological investigations; surveillance, vaccine import, management, and distribution; and technical support and education;
2. The Provincial Animal Health Authority supports on-farm clinical diagnosis and implementation of control measures, such as disinfection and movement restrictions;
3. The Ministry of Information and Communication assists with communication and public awareness campaigns;
4. The Ministry of National Defense enforces movement restrictions and manages stamping out operations;
5. The National Police Agency also helps with enforcement of movement restrictions;
6. The Korea Customs Service helps prevent the illegal entry of livestock and livestock products through commercial and noncommercial channels; and
7. The National Maritime Police Agency assists with the prevention of illegal entry of livestock and livestock products.

Conclusions: The Republic of Korea has the infrastructure and legal authority to declare an animal health emergency and take appropriate action in case of an FMD outbreak. The disease control authority, programs, and animal health management appear adequate. Emergency response capacity appears well planned, documented, and readily implemented. NVRQS tested its emergency response capacity during the 2002 FMD outbreak and quickly controlled the outbreak. Korea incorporated the lessons learned from the 2002 outbreak into the current emergency response plan for FMD.

RELEASE ASSESSMENT: SUMMARY OF RISK FACTORS AND MITIGATIONS CONSIDERED

APHIS identified risk factors that might be associated with importing beef from the Republic of Korea to the United States. APHIS presents these risk factors in context of potential counterbalancing circumstances or by applying appropriate risk mitigations to reduce the risk of introducing and establishing FMD in the United States.

THE LIKELIHOOD OF FMD INTRODUCTION INTO THE REPUBLIC OF KOREA

Risk Factor

FMD is endemic in much of Asia. Consequently, there is an ongoing risk of reintroducing FMD to the Republic of Korea from adjacent affected areas. Therefore, there is a risk that FMD-susceptible species or products from such species destined for the United States could originate from or be commingled with animals or animal products from these affected areas. At least two distinct strains of type O FMD virus are circulating in East Asia. One is a pig-adapted strain present in several countries in South-East Asia, and the other is not specific to a particular species but may be difficult to diagnose because of the variability of clinical signs.

Discussion

The Republic of Korea authorities do not allow live cattle or swine to enter the country unless they are from countries declared to be free of FMD without vaccination by OIE. The only exception is for animals used for breeding, and then only after extensive testing and quarantine.

Conclusion: Beef or beef products, and probably only Hanwoo beef specifically, are South Korea's major potential exports to the United States from FMD-susceptible animals. We do not expect Korea to export products from other FMD-susceptible animals to the United States. APHIS has not evaluated the animal health status of swine for diseases other than FMD; therefore, live swine and swine products are not eligible for import.

Mitigations

APHIS requires that a full-time salaried veterinary officer of the Republic of Korea Government certify that beef or beef products eligible for exportation to the United States did not originate from or were commingled with other beef or beef products originating from outside the Republic of Korea.

THE LIKELIHOOD OF DETECTING FMD IF REINTRODUCED INTO THE REPUBLIC OF KOREA

Risk Factor

1. Farms in the Republic of Korea are primarily small establishments with little pasture and therefore receive routine supervision. This frequent close observation of animals and the routine on-farm inspection by the local veterinarian greatly reduces the likelihood that observers might miss clinical signs of disease.

   Discussion: Producers, animal caretakers, transporters, and other industry staff are well aware of FMD or other vesicular disease symptoms, reporting requirements, and available resources to avoid the disease. Routine examination of livestock during on-farm visits is a part of official surveillance programs. In addition, animals are also inspected at markets and before and after slaughter.

   Conclusion: Husbandry and surveillance practices in the Republic of Korea serve to mitigate the risk of missing FMD clinical signs in export herds.

2. The Republic of Korea is not self-sufficient in meat production. Producing less than half its total beef consumption, it imports the rest and imports roughly one-third of its milk and pork products. Are there risks of disease incursion due to the Republic of Korea importing fresh or frozen beef, mutton, or pork; cooked and uncooked processed meat products; milk or dairy products; hides, skins, and trophies from countries the United States does not consider FMD free?

   Discussion: Korea has adequate import requirements that are sufficiently monitored and well enforced. Border officials are well aware of FMD or other vesicular disease symptoms, reporting requirements, and available resources to avoid the disease.

   There are mitigations available in APHIS' regulations:
   (a) To ensure that there is no commingling of meat and meat products with those destined for export to the United States, and to ensure the country-of-origin of those meat products, the importation of fresh and processed meat from the Republic of Korea into the United States must meet the requirements listed in 9 CFR 94.11. Because the Republic of Korea is considered affected with classical swine fever, fresh (chilled or frozen) pork cannot be imported from that country into the United States.

   (b) Regarding the importation of hides, skins, wool, and hair from the Republic of Korea, the United States restricts their importation under 9 CFR 95.5 and 95.7, ensuring that these products will originate from the Republic of Korea and not from other regions that the United States considers to be affected with FMD. In addition, requirements in 9 CFR 95.11 and 95.12 for bones, horns, and hoofs for trophies are sufficient to ensure that these items are properly treated prior to entry into the United States. Alternatively, these commodities could be imported into the United States by permit, which would include certification requirements as to the country/region-of-origin.

   (c) As to the Republic of Korea importing milk and milk products from countries the United States considers FMD-affected, the requirements listed in 9 CFR 94.16(d) are adequate to ensure certification of the country-of-origin of the production and processing of these products imported into the United States.

   Conclusion: Importation controls and inspection practices in the Republic of Korea serve to mitigate the risk of missing FMD clinical signs in export herds. In addition, the requirements in place for importation into the United States further serve to mitigate the risk.

RELEASE ASSESSMENT: CONCLUSION

Based on an evaluation of the 11 factors and observations from the site visit, APHIS considers that the Republic of Korea has the legal framework, animal health infrastructure, disease detection capabilities, reporting systems, and emergency response systems that are necessary for maintaining the Republic of Korea as free of FMD.

EXPOSURE ASSESSMENT

Exposure assessment describes the biological pathway(s) necessary for the exposure of animals and humans in an importing country to hazards released from a given risk source and estimates the probability of the exposure(s) occurring, either qualitatively or quantitatively [19]. The following sections describe the likelihood of the exposure of U.S. animals and humans to the FMD virus through the importation of contaminated meat, infected live animals, and embryos.

Exposure through the importation of FMD-infected beef

HanWoo beef is the major product that the Republic of Korea is likely to export to the United States. APHIS considers the most likely pathway of exposure of domestic livestock to FMD in beef is through feeding of contaminated food waste to swine. APHIS reviewed previous VS studies [20] to evaluate the likelihood of exposure of FMD-susceptible species to FMD-infected beef, which could happen if FMD-infected beef were imported. In 1995, VS conducted a pathway analysis to estimate the likelihood of exposing swine to infected waste [21]. The analysis included two pathways for exposure of swine: exposure associated with illegal household imports and exposure associated with legal imports. VS estimated with 95 percent confidence that 0.023 percent or less of plate and manufacturing waste would be inadequately processed before it is fed to swine [21]. Based on this fraction, less than 1 part in 4,300 of imported beef is likely to be fed to swine as inadequately cooked waste.

VS conducted a survey in 2001 of the U.S. swine waste-feeding sector to update a similar study done in 1994 [22]. Based on this survey, VS estimated that the proportion of plate and manufacturing waste fed to swine diminished by about 50 percent between 1994 and 2001 due to a decrease in the number of waste-feeding premises. The study also found that:

- The number of waste-feeding premises has decreased significantly since 1994;
- Several States have prohibited feeding food wastes to swine;
- The continental United States had a 40.5 percent decrease in the number of waste-feeding premises, Hawaii a 37.5 percent decrease, and Puerto Rico a 52.3 percent decrease; and
- Institutions and restaurants provide nearly 90 percent of all plate waste fed to swine.

APHIS considers that prohibiting the feeding of unprocessed plate waste to swine has further contributed to this reduction. In that regard, waste-feeder operations must be licensed and inspected regularly by USDA inspectors (9 CFR 166) [23]. The licensing process requires that producers adequately cook the waste fed to swine according to methods designed to reduce the probability of survival of foreign animal disease agents.

Based on the 1995 estimate that a very small proportion of food waste is inadequately processed before it is fed to swine, and the substantial reduction in waste-feeding operations in recent years, APHIS considers the likelihood of exposure of susceptible swine to FMD through inadequately processed food waste to be low. Based on the results of the release assessment, APHIS further considers the likelihood of exposure of susceptible swine to FMD through importing inadequately cooked infected beef from the export region to be low.

Exposure to FMD virus through importation of live susceptible species

The likelihood of exposure of susceptible species to infected live animals was evaluated by briefly reviewing virus persistence and shedding in live ruminants and swine, as well as standard import requirements for these species. Considering the Republic of Korea's disease control program, the likelihood of introducing these animals is extremely low since they will likely be detected. In the unlikely event that infected animals (undetected animals) were imported, they are required to undergo quarantine, which will mitigate that risk pathway. Only animals that have not been vaccinated for FMD are eligible for import, and infected unvaccinated animals will develop clinical symptoms of the disease if under quarantine for 30 or more days.

Current U.S. regulations require certification that ruminants and swine have been kept in a region entirely free of FMD for 60 days prior to export (9 CFR 93.405 and 93.505) and require a minimum quarantine of 30 days for most imported ruminants (9 CFR 93.411) and 15 days for all imported swine (9 CFR 93.510) from the date of arrival at the port of entry. These requirements serve to partially mitigate the risk of exposure by increasing the probability of disease detection.

Based on the conclusion of the release assessment that diseased animals are not likely to exist in the Republic of Korea, APHIS considers the probability of exposure of susceptible U.S. animals to FMD virus via importation of infected susceptible species from that country to be negligible.

Exposure to FMD virus through the importation of genetic material

Genetic materials have been implicated in the introduction of foreign animal diseases into susceptible populations, as well as the spread of established disease epidemics over considerable distances.

Embryos present a negligible risk of infecting exposed recipients with FMD, since the zona pellucida is an important barrier against pathogens, and only zona-pellucida-intact bovine embryos are permissible in international trade [24]. Furthermore, embryo washing is considered to significantly reduce the risk of FMD if present. FMD virus may be present in semen up to 4 days before clinical signs become apparent [1]. However, if the donor animal develops clinical signs, it would then be unlikely that embryos or semen would be collected from a diseased donor or an infected herd. Finally, if FMD were detected in the Republic of Korea, APHIS would ban the importation of animals and animal products until we could reevaluate the country's FMD status. Therefore, APHIS considers the risk of transmission of FMD via embryos negligible.

However, due to the extended period of survival of FMD virus in frozen semen, APHIS considers there is a likelihood of exposure of susceptible animals to this virus in infected semen if imported from the Republic of Korea. However, based on the conclusion of the release assessment that FMD is not likely to be present or go undetected in that country, APHIS considers exposure of a susceptible U.S. animal population to imported infected semen or embryos from Korea highly unlikely.

Exposure Assessment: Conclusion

Based on pathway analyses, APHIS concluded that the likelihood of exposure of susceptible U.S. swine to FMD virus through inadequately processed food waste to be low. Evidence that only a very small proportion of food waste is inadequately processed before it is fed to swine and the substantial reduction in waste-feeding operations in recent years supports this conclusion. Furthermore, based on the conclusion of the release assessment that diseased animals are not likely to exist in the Republic of Korea, APHIS considers the probability of exposure of susceptible swine to these viruses through inadequately cooked infected meat from this country to be low.

In addition, APHIS considers the likelihood of exposure of susceptible U.S. ruminants or swine to FMD virus via infected live ruminants or swine from the Republic of Korea to be low. According to APHIS regulations, once a country is listed as FMD-free following USDA's risk analysis, other requirements must be met to import live ruminants into the United States. These requirements include the following:

- The ruminants must be accompanied by a health certificate issued by a full-time salaried veterinary officer of the national government of the region of origin.
- The ruminants must have been kept in that region during the last 60 days immediately preceding the date of shipment to the United States.
- The ruminants are not in quarantine in the region of origin.
- The ruminants must meet the tuberculosis and brucellosis testing requirements stated in 9 CFR 93.406.
- All ruminants imported into the United States (except those from Canada, Mexico, Central America, and the West Indies) must be quarantined for not less than 30 days starting from the date of arrival at the port of entry.

These requirements serve to mitigate the risk of exposure by increasing the probability of disease detection prior to export and during quarantine in the United States.

Based on the conclusion of the release assessment that diseased animals are not likely to exist in the Republic of Korea, APHIS considers it highly unlikely that infected animals or animal products would be exported. Therefore, the exposure of a susceptible U.S. animal population to imported infected semen or embryos from this country would be highly unlikely.

Ultimately, the requirements in 9 CFR 94.11 mitigate the risks associated with less restrictive trade practices by:

(1) Restricting the sourcing of ruminant meat for export;
(2) Prohibiting the commingling of live animals, meat, or meat products for export with commodities from regions not considered free of these diseases; and
(3) Requiring exporting slaughter establishments to be approved by USDA's Food Safety and Inspection Service.

In addition, an official veterinarian of the exporting country must certify that these conditions have been met.

CONSEQUENCE ASSESSMENT

A consequence assessment describes the biologic and economic consequences of FMD introduction into the United States. This consequence assessment addresses both direct and indirect consequences as recommended by the OIE [19].

The magnitude of the biologic and economic consequences following an introduction of FMD would depend on the location of the introduction, the FMD virus serotype introduced, the rate of spread of FMD and whether other environmental conditions exist at the introduction site that might facilitate this spread, the ability to detect the disease rapidly, livestock demographics and movement patterns, and the ease of employing eradication procedures [25]. In addition, depending on the extent of exports of livestock and their products, trade restrictions imposed by trading partners often result in severe economic consequences.

Direct consequences

Direct consequences include effects of the disease on animal health and the subsequent production losses, the total costs of control and eradication, the effect on the environment, and public health consequences.

Effects on animal health and production

FMD causes significant distress and suffering to animals regardless of the size and sophistication of their livestock unit. Very high mortality rates in young animals can occur, particularly among pigs and sheep [26]. In pigs, Dunn and Donaldson (1997) [27] estimated a general mortality rate of 40 percent for two outbreaks in Taiwan in 1997. Geering (1967) [28] cites mortality rates of 40, 45, and 94 percent of lambs in several outbreaks. Mortality in older animals occurs less frequently but may be significant with certain virus strains.

FMD causes significant losses in the production capacity of affected animals. Productivity losses of 10 to 20 percent are reported in FMD-infected livestock [25] if the disease is allowed to run its course. For example, the drop in milk yield of dairy cattle averages approximately 25 percent per year [29]. In addition, FMD can cause a reduction in the growth rate of animals raised for meat. According to Doel (2003) [30], estimates vary considerably, but one study indicated that cattle would require approximately 10 to 20 percent longer to reach maturity. The comparatively greater severity of FMD in pigs would imply at least similar losses to those described for cattle.

Control and eradication costs

The overall cost of control and eradication depends on the mitigation or policy option chosen. Potential costs include imposing quarantine measures and movement controls, stamping out of affected and other herds, indemnity payments, vaccination costs, surveillance and laboratory testing, etc.

For disease-free countries like the United States that have a substantial export market for livestock and livestock products, the preferred option for control and eradication has traditionally been to stamp-out affected herds without the use of vaccine. The U.S. policy for FMD emergencies is to follow strict quarantine measures and stamping-out of affected and contact herds with ongoing analysis for the need for and implementation of strategic vaccination.

Published studies indicate that where FMD eradication without vaccination is feasible, it is the least-cost policy option, even allowing for the costs of prevention and emergency preparedness and the risk of outbreaks. However, if the extent of the outbreak were large or if the disease were spreading at a fast rate, vaccination might be beneficial in protecting high-producing livestock [31]. A recent study using a stochastic simulation model showed that ring vaccination decreased the duration of outbreaks. However, depending on the magnitude of the outbreak and the number of herds involved, the time and cost needed to dispose of vaccinated animals could be substantial [32].

Available data do not allow quantification of the number of herds or farms that would be infected if FMD were introduced. Nevertheless, the cost of control, eradication, and compensation is likely to be significant. Bates et al (2003) [33] used results from an FMD simulation model to estimate the direct costs associated with indemnity, slaughter, cleaning, and disinfecting livestock premises for various vaccination and eradication strategies to control transmission of FMD in a cattle population of 2,238 herds and five sale yards located in three counties of California. The study found that mean herd indemnity payments were $2.6 million and $110,359 for dairy and nondairy herds, respectively. Cleaning and disinfection costs ranged from $18,062 to $60,205 per herd. The mean vaccination cost was $2,960 per herd and the total eradication cost ranged from $61 million to $551 million depending on eradication strategy.

At the national level, McCauley, et al. (1979) [25] conducted a comprehensive study to assess the potential economic impact of FMD in the entire United States. The study estimated the direct costs (control and eradication program costs) and increased costs borne by consumers over a 15-year period (1976-1990). The study examined several control and eradication options. Relevant to this analysis are strategies employed to eradicate the disease by stamping out or area vaccination. In the extreme event of endemic FMD in the United States, the study also considered the impact of compulsory or voluntary control programs. Table 11 shows a summary of the findings. The results were updated using the difference in the consumer price index (CPI) in 2001 [34].

Table 11. Economic impacts of FMD adjusted from 1976 dollars to 2007 dollars by the CPI[1].

	Consumer Impacts		Program Costs		Totals	
	millions of dollars					
FMD cost estimates from McCauley et al., 1979 [25]	*1976$*	*2007$*	*1976$*	*2007$*	*1976$*	*2007$*
Endemic FMD w/ voluntary control	$11,600	$42,270	na	na	$11,600	$ 42,270
Eradication by strict slaughter and quarantine	$10,600	$38,626	$539	$1,964	$11,139	$ 40,590
Eradication by area vaccination	$10,600	$38,626	$690	$2,514	$11,290	$ 41,140
Compulsory vaccination program w/ endemic FMD	$8,900	$32,431	$4,200	$15,305	$13,100	$ 47,736

[1]Adjusted 2007 \$ = 1976 \$ x CPI_{2007}/CPI_{1976}, where CPI_{2007} = 207.34 and CPI_{1976} = 56.9 (Source: Bureau of Labor Statistics, U.S. Department of Labor)
Source: Adapted, McDowell 2001, personal communication.

Effect on the environment

A separate but related environmental assessment (APHIS proposed rule) has considered the environmental effects under all applicable environmental review laws in force in the United States. The environmental assessment complies with the National Environmental Policy Act (NEPA) and implementing regulations [35].

Effect on public health

Although public health consequences are not under APHIS' regulatory authority, we address the issue in this analysis. FMD rarely affects humans. The number of cases reported is so small when compared with the number of persons exposed that FMD is generally not considered a threat to humans. FMD virus has been isolated and typed in only 40 patients during the last century. Symptoms in humans are mostly mild and mainly include fever and blisters on the hands, feet, mouth, and tongue. Patients usually recover within a week after the last blister formation [36].

Perhaps more importantly, an FMD outbreak of the magnitude observed in the United Kingdom can result in severe psychosocial effects on farmers and farming communities. Farmers and their families can suffer grief over losing animals, in some cases blood lines kept over many generations, as well as loss of control over their lives due to movement restrictions, disruptions in community life, and short- and long-term stress over their financial future. Researchers from Lancaster University in the United Kingdom conducted a new study into the social consequences of FMD in the Cumbria community, which revealed high rates of depression, alcohol consumption, and mortality among farmers during the crisis (Lancaster University, Unpublished report) [37].

Indirect consequences

In addition to the direct costs of FMD introduction, impacts on international trade and related domestic consequences should be considered. Export losses due to restrictions imposed by trade partners on FMD-susceptible animals and products can run into billions of U.S. dollars. The value of U.S. exports of beef products alone, which would be immediately lost, was over $3 billion in 2001. The impact of an outbreak of FMD on the rural and regional economic viability, including businesses reliant on livestock revenue, could also be substantial.

In 2002, Paarlberg, et al. [38], conducted a study to estimate the potential revenue impact of an FMD outbreak in the United States similar to the one that occurred in the United Kingdom. The study suggested that the greatest impact on farm income would be due to loss of export markets and the decrease in demand by consumers. For example, losses of gross revenue for the animal sector were as follow: cattle (17 percent), beef (20 percent), milk (16 percent), swine (34 percent), pork (24 percent), sheep and lambs (14 percent), and sheep and lamb meat (10 percent). Thompson, et al. (2002) [39], estimated the FMD outbreak in the United Kingdom caused the loss of about 20 percent of the estimated total income from farming in 2001.

Japan, Korea, and Mexico constitute the three major U.S. export markets for ruminant products. The value of lost exports to these markets would total $3 billion annually if trade restrictions were enforced against the United States: Japan ($1.2 billion); Mexico ($1.12 billion); and South Korea ($712 million). Indirect economic losses to U.S. firms that support ruminant exports to these markets would equal an additional $2.5 billion annually. The magnitude of these values reflects both animal and product exports [38].

More than 33 thousand full-time U.S. jobs, accounting for almost $1 billion in wages annually, could be jeopardized by loss of these three markets. In the longer term, if trade restrictions persisted and alternative export markets did not develop, the U.S. ruminant production sector could contract, allowing other supplying countries to establish trade relationships in the absence of U.S. supply [39].

Other losses, due to restrictions on live swine, pork, and pork products, are likely to be significant as well. The U.S. exports of pork and pork products were estimated at $1.3 billion dollars in 2003 [40] Since the United States exports only small amounts of lamb and mutton, economic losses associated with these commodities are not likely to be significant.

RISK ESTIMATION

Risk estimation consists of integrating the results from the release assessment, exposure assessment, and consequence assessment to produce overall measures of risk associated with the hazards identified at the outset. Thus, risk estimation takes into account the whole risk pathway from hazard identified to the unwanted event [19].

From the analysis, APHIS concludes that the surveillance, prevention, and control measures implemented by the Republic of Korea are sufficient to minimize the likelihood of introducing

FMD or rinderpest into the United States via imports of susceptible species or their products. In addition, APHIS has considered the mitigating effects of the requirements for importing animals and animal products into the United States. Although the potential consequences of a FMD outbreak are substantial, the likelihood of an outbreak occurring via exposure of the domestic livestock population to animal products imported from the Republic of Korea is negligible.

The consequences of a FMD outbreak in the United States would be extremely high. The major economic consequence of importing FMD would be export trade losses. The sum of the consumer impacts, direct costs, and trade losses over a 15-year period would be $37 to $44 billion, in 2001 dollars, depending on the magnitude of the outbreak and eradication strategy. Although such consequences are significant, it is important to note that the results of both the release and exposure assessment indicated that the likelihood of introduction and establishment of FMD is extremely low.

In summary, although the consequences of an FMD outbreak in the U.S. would be very high, given the findings of the release and exposure assessments, APHIS considers the risk of FMD-infected animals or products entering the United States from the export region and exposing U.S. livestock through feeding of infected materials to susceptible animals, to be negligible.

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Appendix 1. Epidemiologic characteristics of foot-and-mouth disease (FMD)

Etiologic Agent
Family *Picornaviridae*, Genus *Aphthovirus*, types O, A, C, SAT1, SAT2, SAT3, and Asia 1.

Status in the United States
FMD virus was eradicated from the United States in 1929.

Epidemiology
FMD is a highly communicable disease of cloven-hoofed animals caused by an *Aphthovirus* of the family *Picornaviridae*. FMD has seven immunologically distinct serotypes (O, A, C, SAT1, SAT2, SAT3, and Asia 1). The O, A, and C serotypes have historically been found in South America [1]. Research indicates that one serotype does not confer protective immunity against the other six, thus a disease outbreak can be caused by one serotype or a combination of serotypes [2].

FMD virus serotype O (PanAsia strain) has been isolated in over 60 percent of positive samples received by the World Reference Laboratory for FMD in the United Kingdom (Institute for Animal Health, Pirbright Laboratory). Along with being the most prevalent type O strain, the PanAsia strain is also the most widely distributed, causing FMD outbreaks in many parts of Africa, Asia, and South America as well as in Europe since 1998. This virus strain can infect a wide range of species including cattle, water buffalo, pigs, sheep, goats, and gazelle [3-5].

FMD virus can be transmitted by direct or indirect contact or aerosol. Fomites (such as feed, drinking water, equipment, animal products, as well as human clothing, transportation vehicles, rodents, stray dogs, wild animals, and birds) can transmit FMD over long distances. The five main elements that influence the extent of FMD spread are:
(1) The quantity of virus released;
(2) The means by which the virus enters the environment;
(3) The ability of the agent to survive outside the animal body;
(4) The quantities of virus required to initiate infection at primary infection sites; and
(5) The period of time the virus remains undetected [6, 7].

The incubation period of the FMD virus is 2 to 14 days in cattle, depending on the viral strain and dose and the level of susceptibility of the animal [8]. Morbidity in unvaccinated herds can be high, but mortality usually does not exceed 5 percent. If it occurs during the calving season, calf mortality can be considerable [9]. Young calves may even die before the development of clinical signs usually because the virus attacks the heart muscles [8].

The respiratory tract is the usual route of infection in species other than pigs. Infection can also occur through abrasions of the skin or mucous membranes. In cattle and sheep, the earliest sites of virus infection and possibly replication appear to be in the mucosa and the lymphoid tissues of the pharynx. Following initial replication in the pharynx, the virus then enters the bloodstream. Viremia in cattle lasts for 3 to 5 days; as a result, the virus spreads throughout the body and establishes sites of secondary infections [10].

The usual route of infection in pigs is through the ingestion of FMD virus-contaminated products, or direct contact with infected animals, or heavily contaminated environments. The incubation period in pigs will vary with the strain, dose, and route of infection. Serotype O, which is highly virulent in pigs, can produce clinical signs within 18 to 24 hours while pigs with low-level exposures may take up to 11 days to develop clinical signs. Pigs that recover from FMD infection do not become carriers as was thought with ruminants [11].

FMD virus localizes in various organs, tissues, body fluids, bone marrow, and lymph nodes [12, 13]. Viral replication may reach peak levels as early as 2 to 3 days after exposure. Virus titers differ in different organs or tissues. Some tissues, such as the tongue epithelium, have particularly high titers. Recent data indicate that the most viral amplification occurs in the stratified, cornified squamous epithelia of the skin and mouth (including the tongue). Although some viral replication also occurs in the epithelia of the pharynx, the amount of virus produced there is apparently much less than the amount produced in the skin and mouth during the acute phase of the disease. By comparison, the amount of virus (if any) produced in other organs like salivary glands, kidneys, liver, and lymph nodes is negligible [14, 15].

Immunity to FMD is primarily mediated by circulating antibodies [16]. The host reaction, including antibody production, occurs from 3 to 4 days after exposure. In infected pigs, the virus is cleared in less than 3 to 4 weeks. In contrast, around 50 percent or more of cattle will develop a low-level persistent infection, localized to the pharynx [17-19]. According to Alexandersen (2002) [16], a model for progression of infection starts with virus exposure, then accumulation of virus in the pharyngeal area, followed by the initial spread through regional lymph nodes, and then spreads via the blood stream to epithelial cells. Several cycles of viral amplification and spread follows [16].

Clinical signs in cattle during acute infection include fever, profuse salivation, and mucopurulent nasal discharge. The disease is characterized by development of vesicles on the tongue, hard palate, dental pad, lips, muzzle, gum, coronary band, and interdigital spaces. Vesicles may develop on the teats. Affected animals lose condition rapidly, and there is a dramatic loss of milk production [8]. The animal usually recovers by 14 days post infection provided no secondary infections occur [10]. The most consistent clinical signs in pigs are lesions around the coronary bands and lameness, but fever may be inconsistent. Pigs may develop vesicles on the tongue and snout, but these may be less conspicuous than lesions seen in ruminants. The severity of clinical disease depends on the age of the infected pig. Adult swine may recover or become chronically lame while younger pigs, especially those less than 8 weeks of age, may die from acute myocarditis without developing other clinical signs [11, 17].

Diagnosis of the disease relies heavily on recognizing clinical signs. In unvaccinated cattle and pigs, the clinical signs are obvious. However, in small ruminants the disease is often subclinical or is easily confused with other conditions. In addition, in endemic regions, clinical signs in partially immune cattle may be less obvious and could pass unnoticed [8]. Virus isolation and serotype identification are necessary for confirmatory diagnosis. The clinical signs of FMD are similar to those seen in other vesicular diseases. Differential diagnosis of vesicular diseases includes vesicular stomatitis, mucosal disease of cattle, bluetongue, rinderpest, and FMD. Serological diagnostic tests include the complement-fixation test, virus neutralization test, and an enzyme-linked immunosorbent assay test. Other diagnostic tests include one- or two-dimensional electrophoresis of the viral DNA, isoelectric focusing of the viral structural proteins, or nucleotide sequencing of the viral RNA [7].

FMD virus is a relatively resilient virus. It can survive up to 15 weeks in feed, 4 weeks on cattle hair, and up to 103 days in wastewater. The survival of the virus in animal tissues is closely associated with the acidity of that tissue. For example, in muscular tissues the acidity of rigor mortis, which occurs naturally, inactivates the virus. The production of lactic acid in these tissues during maturation is considered the primary factor for inactivation [20]. An acid environment where the pH is less than 6.0 will destroy the virus quickly [20, 21]. Several studies showed that in tissues where no acidification occurs (e.g., lymph nodes, bone marrow, fat, and blood), the virus may survive for extended times in cured, uncured, and frozen meat [13, 20-23]. Heating at 50° C [24] and up to 155° F [25] will inactivate the virus.

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Appendix 2. Epidemiologic characteristics of rinderpest

Etiologic Agent
Family *Paramyxoviridae*, Genus *Morbillivirus*

Status in the United States
The United States has been historically free from rinderpest.

Distribution
Historically, the virus was widely distributed throughout Europe, Africa, Asia, and West Asia, but never became established in either the Americas or Australia/New Zealand. Rinderpest is an OIE listed disease [1]. In Africa it has been eradicated from several countries and sub-regions, and is normally absent from the northern and southern parts of the continent. Rinderpest occurs in the Middle East and in southwestern and central Asia.

Epidemiology
Rinderpest is a highly fatal viral disease of domestic cattle, buffaloes, and yaks. It also affects sheep, goats, and some breeds of pigs (Asian pigs seem more susceptible than African and European pigs). Rinderpest can infect a large variety of wildlife species, including African buffaloes, eland, kudu, wildebeest, various antelopes, bushpigs, warthogs, and giraffes, but is rare among camelids.

Transmission of rinderpest can occur through direct or close indirect contacts. The usual route of infection is via the respiratory tract with an incubation period of generally 4 to 5 days following natural exposure, but may range from 3 to 15 days. Viral shedding begins 1 to 2 days before pyrexia in tears, nasal secretions, saliva , urine, and feces and typically continues for 8 to 9 days after the onset of clinical signs. Blood and all tissues are infectious before the appearance of clinical signs.

Rinderpest can take several clinical presentations: classic, peracute, subacute, and atypical. There is no carrier state following infection. The classic form is characterized by a 2- to 3-day period of high fever, depression, anorexia, reduced rumination, increased respiratory and cardiac rate, congested mucus membranes, intense mucopurulent lachrymation, and excessive salivation. Gastrointestinal signs appear when the fever drops with profuse hemorrhagic diarrhea. Dehydration, abdominal pain, abdominal respiration, weakness, recumbency, and death generally occur within 8 to 12 days. In rare cases, clinical signs regress by day 10 and recovery occurs by day 20 to 25.

The peracute form has no prodromal signs and is characterized by high fever (>40 to 42°C) and death. The peracute form occurs in highly susceptible young and newborn animals. The subacute form has a low mortality rate and a similar clinical presentation to the classic form. The atypical form is characterized by irregular pyrexia with mild or no diarrhea.

Rinderpest virus is relatively resistant and is stable between pH 4.0 and 10.0, but is susceptible to most common disinfectants including lipid solvents. The virus remains viable for long periods in chilled or frozen tissues. Small amounts of rinderpest virus may survive relatively high temperatures: 56°C (133°F) for 60 minutes or 60°C (140°F) for 30 minutes.

Differential diagnosis of rinderpest is similar to that of other viral vesicular diseases including FMD, bovine viral diarrhea/mucosal disease, infectious bovine rhinotracheitis, malignant catarrhal fever, vesicular stomatitis, and in small ruminants, peste des petits ruminants.

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Appendix 3. Schematic of Animal Quarantine Facilities on Youngjong Island